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Outcome of the public consultation on the draft guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003

Andersson, Christer ; Gropp, Jürgen ; Naegeli, Hanspeter ; Nogué, Fabien ; Rostoks, Nils ; Sweet, Jeremy ; Dumont, Antonio Fernandez ; Gomes, Ana ; Mestdag, Sylvie ; Paoletti, Claudia ; Ramon, Matthew ; Waigmann, Elisabeth

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TECHNICAL REPORT

Outcome of the public consultation on the draft guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003¹

European Food Safety Authority^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

A public consultation on the draft guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003 endorsed by the Panel on Genetically Modified Organisms of the European Food Safety Authority was launched on 4 November 2014 and ended on 4 January 2015. The European Food Safety Authority received 114 comments on this draft guidance from 20 interested parties. Through its dedicated working group, the Panel on Genetically Modified Organisms scrutinised and assessed all comments falling within the remit of the European Food Safety Authority. Where appropriate, the draft guidance was revised to take into account relevant comments. This technical report summarises the most relevant comments received during the public consultation and outlines how these were taken into account when producing the final document.

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KEY WORDS

renewal authorisation, GM food and feed, Regulation (EC) No 1829/2003, Articles 11 and 23

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SUMMARY

On 22 October 2014, the Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) endorsed a draft guidance for renewal applications of genetically modified (GM) food and feed authorised under Regulation (EC) No 1829/2003. Subsequently, the draft guidance was released for public consultation on 4 November 2014; this consultation period ended on 4 January 2015.

EFSA received 114 comments on this draft guidance from 20 interested parties (i.e. institutes, non-governmental organisations, associations, industry organisations, and international and national risk assessment bodies). The EFSA GMO Panel, through its dedicated working group for the development of a guidance document for the risk assessment of GMO renewal applications, scrutinised all comments. All public comments, falling within the remit of EFSA, were assessed and the draft guidance was revised taking into account relevant comments.

EFSA committed to publish a technical report on the outcome of this consultation on the draft guidance. This technical report summarises the most relevant comments received through the public consultation and outlines how these were taken into account when producing the final document.

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BACKGROUND AS PROVIDED BY EFSA

According to Articles 11(6) and 23(6) of Regulation (EC) No 1829/2003⁴ on GM food and feed, EFSA shall publish detailed guidance to assist the applicant in the preparation and presentation of their applications for the renewal of authorisations of GM food and feed (hereafter referred to as ‘renewal applications’).

On 18 July 2013, the EFSA GMO Panel proposed to EFSA to establish a self-tasking working group with the aim of developing risk assessment guidance for renewal applications of GM food and feed authorised under Regulation (EC) No 1829/2003. On 26 July 2013, the proposal was accepted by EFSA and the renewal guidance working group had a first meeting on 9 December 2013⁵.

At its plenary meeting of 22 and 23 October 2014, the EFSA GMO Panel endorsed a draft guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003.

In line with EFSA’s policy on openness and transparency, and in order for EFSA to receive comments from the scientific community and stakeholders on its work, EFSA engages in public consultation on key issues (see Appendix A). Accordingly, the draft guidance was released for public consultation on EFSA’s website⁶ from 4 November 2014 until 4 January 2015. Stakeholders were informed and invited to submit comments. All comments are listed in Appendix B.

EFSA has committed to publish a technical report on the outcome of the consultation on the draft guidance. This technical report summarises the relevant comments received through the consultation and outlines how these were taken into account in the final Guidance document.

The EFSA GMO Panel considered all scientifically relevant comments from the public when finalising its guidance document. The EFSA GMO Panel did not consider issues related to risk management, risk–benefit, ethical and socio-economic aspects as those are outside its remit.

TERMS OF REFERENCE AS PROVIDED BY EFSA

The EFSA GMO Panel is asked:

- to prepare a guidance document for the risk assessment of GM food and feed already authorised under Regulation (EC) No 1829/2003 in the frame of the renewal of authorisations;
- to consult the public in the frame of a public consultation;
- to review the draft guidance document considering the relevant comments gathered from the public consultation.

⁴ Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. OJ L 268, 18.10.2003, p. 1–23.

⁵ <http://www.efsa.europa.eu/en/gmowgs/documents/guidanceRAofGM1829-2003.pdf>

⁶ <http://www.efsa.europa.eu/en/consultationsclosed/call/141104.htm>

1. Introduction

During the public consultation period, EFSA had received 114 comments from 20 interested parties (i.e. institutes, non-governmental organisations, associations, industry organisations, and international and Member State risk assessment bodies). Comments within the remit of EFSA were considered by a dedicated working group from the EFSA GMO Panel when preparing the final guidance document for renewal applications GM food and feed authorised under Regulation (EC) No 1829/2003. The comments related to the draft guidance document were compiled, along with references to the relevant contributors and to the section of the draft scientific opinion to which the comment refers (see Appendix B). Any comments submitted formally on behalf of an organisation appear along with the name of the organisation.

2. Screening and evaluation of comments received

2.1. General comments

Overall, the public comments on the draft guidance document expressed contrasting views. On the one hand, some stakeholders perceived that the draft guidance document lacks the necessary data requirements to bring renewal applications in line with the latest EFSA guidances (EFSA GMO Panel, 2010a, b, 2011) and Commission Implementing Regulation (EU) No 503/2013⁷, and suggested more elaborate data requirements. On the other hand, some stakeholders challenged the legality of the mandatory data requirements described in the draft guidance document, based on the interpretation of Articles 11 and 23 of Regulation (EC) No 1829/2003.

Some comments questioned the general GMO risk assessment principles that are described in diverse EFSA guidance documents and Commission Implementing Regulation (EU) No 503/2013, and formulated several recommendations for revisiting these principles. In addition, the need for a renewal procedure after 10 years of authorisation was questioned by several stakeholders.

Stakeholders provided helpful suggestions with regard to editing the text of the guidance document and clarifications, and proposed changes in terminology (e.g. it was suggested to use the term ‘bioengineered’ or ‘genetically engineered’). Some comments referred to the EFSA GMO Panel’s renewal guidance document adopted in 2006 (EFSA, 2006) and requested clarification on whether the guidance currently being developed will supersede this 2006 guidance document.

Comments on maximum residue limits for herbicides and ethical and commercial aspects of GMOs fall outside the remit of the EFSA GMO Panel and were therefore not addressed.

2.2. Comments on specific sections

Major and/or repeated technical comments related to the specifics addressed in the different sections of the guidance document (EFSA GMO Panel, 2015) are summarised below.

2.2.1. Identification of the transformation event(s)

Several comments questioned the scientific rationale for requesting the identification of the transformation event(s) in renewal applications by resequencing, considering that there is no evidence that genomes of GM plants evolve differently from conventionally bred varieties.

In addition, several comments pointed out that the description of how to select the varieties and geographical areas from which plant material should be sampled is not sufficiently detailed. Also, the number of samples and tissues to be selected is not clearly defined.

⁷ Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006. OJ L 157, 8.6.2013, p. 1–48.

Several stakeholders also requested clarifications on the difference between this identification request and the standard detection method that is submitted with the original application for the release of GM plants in the European market.

Finally, several comments questioned the request for the sequencing of 1 kb regions flanking the insert(s). It was pointed out that this request constitutes a request for the generation of new data.

2.2.2. Post-market monitoring and post-market environmental monitoring reports

Several comments requested a clarification of whether all monitoring reports, covering the years of authorisation, should be submitted. On the one hand, stakeholders were questioning the validity of this request, and, on the other hand, asked for more and independent monitoring.

Some stakeholders asked why post-market environmental monitoring (PMEM) reports need to be provided in the frame of this renewal application since this guidance document only deals with renewal applications for import and processing.

2.2.3. Systematic search and evaluation of literature

Several stakeholders requested that the guidance document should ask for a literature search based on broader search terms, i.e. not confined to the GM trait(s). Some comments requested more clarity with regard to the exact databases to be searched.

At the same time, the need for literature searches was questioned by other stakeholders, as the relevant publications might already be part of the monitoring reports.

2.2.4. Updated bioinformatics

Several stakeholders questioned the validity of asking for updated bioinformatics based on the legal framework laid down by Regulation (EC) No 1829/2003. Other stakeholders welcomed the request for updated bioinformatics, but indicated that bioinformatics for horizontal gene transfer (HGT) is a new requirement and should not be asked for in the frame of a renewal application. In contrast, other stakeholders requested a more elaborate updated bioinformatics package, supported by experimental evidence, for the lack of HGT.

Some comments suggested that updated bioinformatics analyses should be performed with the sequence submitted in the original application for the authorisation of the event(s).

2.2.5. Additional documents or studies performed by or on behalf of the applicant

Several stakeholders asked that specific studies in different research areas should be performed by the applicant. Other comments questioned the need for information on additional studies performed by the applicant, since they would have been retrieved by the systematic search and literature evaluation, or they would have been included in the monitoring reports. Therefore, more clarity was requested regarding the type of studies to be included in a renewal application.

It was also pointed out that the applicant has a legal obligation to inform the European Commission of certain restrictions imposed during the authorisation of the event(s) in third countries and, therefore, should not be asked to do so in the context of renewal applications.

3. Consideration of relevant comments

3.1. Consideration of general comments

The need for a renewal of a GM event(s) that is authorised and has been on the market for 10 years is a legal obligation in the European Union. Articles 11 and 23 of Regulation (EC) No 1829/2003 list the documentation that should be provided in support of renewal applications, clarified by an interpretation by the EC (22 May 2014). The working group worked within these legal boundaries to

prepare a guidance document that details the minimum requirements that should be included in a renewal application to assess whether the original opinion remains valid for the event(s) up for renewal.

Basic risk assessment principles, laid down in different EFSA guidance documents (EFSA GMO Panel, 2010a, b, 2011) and in Commission Implementing Regulation (EU) No 503/2013, were followed by the working group in order to determine the details of the requirements for renewal applications. It was not in the remit of this working group to discuss these basic principles themselves. In addition, since renewing the authorisation of events which have been on the market for 10 years is a legal obligation in the EU, a review of the need for this legal requirement was out with the remit of this working group and was, therefore, not discussed.

Since the previous renewal guidance (EFSA, 2006) dealt only with the renewal of authorisations of existing GM products for food and feed uses, lawfully placed on the market and notified according to Articles 8 and 20 of Regulation (EC) No 1829/2003, this guidance document has a narrow scope and, currently, only a limited applicability. The present guidance document will be applicable for the renewal of all applications for import and processing that fall under Regulation (EC) No 1829/2003.

Relevant suggestions with regard to editing the text of the guidance for the improvement of the document were taken on board where appropriate. However, since the term ‘genetically modified organisms’ is used in Regulation (EC) No 1829/2003, the working group decided to retain this terminology for consistency with wording used in EU legislation.

3.2. Consideration of comments on specific sections

3.2.1. Identification of the transformation event(s)

Upon further clarification from the EC on the interpretation of Articles 11 and 23 of Regulation (EC) No 1829/2003 (11 May 2015), the section requesting information on the identity of the transformation event(s) up for renewal and describing the plant material to be sampled was deleted from the draft renewal guidance, since this requirement is considered outside the legal frame.

Instead, a sentence was added to the introduction of the renewal guidance document stating that the EFSA GMO Panel can examine the validity of its previous risk assessment in the context of the renewal application only if the event(s) for renewal is identical, in its sequence, to the one(s) previously assessed. In order to support such an assumption, the EFSA GMO Panel requests that the applicant includes sequence data on the event(s) for renewal under the section ‘additional documents or studies performed by or on behalf of the applicant’.

Footnote 11 of the introduction section of the renewal guidance document clarifies why the standard detection method that is submitted with the original application for the release of GM plants on the European market is not adequate for determining the sequence of an event.

In case the originally determined flanking regions did not allow to clearly determine whether known endogenous genes were interrupted, because, for example, the flanking region sequences were too short or no suitable reference genome was available, the EFSA GMO Panel recommends a sequencing length of 1 kb on each side of the insert(s). This is based on the estimated average plant intron length, as described by Wu et al. (2013). This recommendation was moved to the updated bioinformatics section of the renewal guidance document (EFSA GMO Panel, 2015).

3.2.2. Post-market monitoring and post-market environmental monitoring reports

In accordance with the legal framework, results from post-market monitoring and/or PMEM should be provided as part of renewal applications. For all authorisations for import and processing that include the placing on the market of live GM material (e.g. grain), it is legally required that PMEM reports are submitted to the EC on a yearly basis. The working group clearly indicated that all monitoring reports

(covering all years of authorisation) submitted by the applicants should be provided to support the assessment of renewal applications.

Independent monitoring activities/studies carried out by parties other than the applicant do not fall under this section but would be identified in the systematic search and evaluation of literature, as described in the guidance document.

3.2.3. Systematic search and evaluation of literature

In order to have a complete overview of the relevant literature published on the GM event(s) to be renewed, the working group confirmed that a thorough literature search is needed for renewal applications. The section on literature database searches was further elaborated as a result of comments requesting more methodological details. It is now clearly stated that the applicant needs to screen the literature for publications relevant for molecular characterisation, food/feed and environmental safety of the event(s) to be renewed. A list of publications, as outcome of the literature search, and a copy of all relevant papers should be provided and discussed with regard to the possible impact on the previous risk assessment.

The applicant is requested to explain the rationale for the choice of databases examined, the search terms used, the total and relevant hit rate, and any restrictions that were applied. These parameters will be assessed by the EFSA GMO Panel for their completeness and validity.

The EFSA GMO Panel also added a new paragraph stating that in case a systematic literature search was performed and documented in the frame of each year of the yearly PMEM reports throughout the full duration of the authorisation period, consistently using the same search terms and databases, the applicant can, instead, provide a summary report of the outcome of these systematic literature searches.

3.2.4. Updated bioinformatics

The working group confirmed that newly available data must be considered during the assessment of renewal applications and therefore considers that the request for updated bioinformatics is valid, taking into account the continuous updates and evolution of the DNA sequence databases used for these bioinformatic searches.

The EFSA GMO Panel maintains its view that bioinformatic analyses to investigate the possibility for HGT to known microorganisms should be considered, similarly to the HGT analyses requested during the pre-market risk assessment. Therefore, and considering the continuous updates and evolution of microbial DNA sequence databases, the GMO Panel specified this in the renewal guidance.

A request for a more extensive bioinformatics data package, including the generation of new experimental evidence, would not be in agreement with the legal frame defined in Regulation (EC) No 1829/2003.

The working group confirmed that the most relevant sequences for the bioinformatics analyses would be those event sequences received under Section 2.3.3 of the renewal guidance document (EFSA GMO Panel, 2015).

3.2.5. Additional documents or studies performed by or on behalf of the applicant

A literature search will not identify unpublished studies. Therefore, the EFSA GMO Panel confirmed that the applicant should list and summarise all unpublished studies produced, controlled or sponsored by the applicant, or provided to the applicant by a third party. Their relevance for molecular characterisation, human and animal safety and the environment should be assessed. Amongst those studies, data on the sequence of the event(s) for renewal, derived from seed lines containing the event(s) and giving rise to varieties imported into the EU close to the time of the renewal application, should be provided.

The working group confirmed the importance of receiving a complete overview of any prohibition or restriction imposed by the competent authority of any third country in which the food and/or feed is placed on the market, including inconclusive opinions.

CONCLUSIONS

All comments received during the public consultation were scrutinised and considered by the EFSA GMO Panel, through its dedicated working group for the development of a guidance document for the risk assessment of GMO renewal applications.

Many comments received were relevant and of high value. These were taken into account by the working group when revising the draft guidance, thereby enhancing the scientific quality and clarity of the guidance document.

The EFSA GMO Panel acknowledges the usefulness and quality of the majority of comments and would like to thank all stakeholders for their interest and input to its current and future work.

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APPENDICES

Appendix A. Text of the public consultation from the EFSA website

Public consultation on the draft guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003

Deadline: 4 January 2015

The European Food Safety Authority's Panel on Genetically Modified Organisms (EFSA GMO Panel) has launched an open consultation on a draft Guidance Document for renewal applications of genetically modified (GM) food and feed authorised under Regulation (EC) No 1829/2003[1].

The aim of this draft Document is to provide guidance on renewal applications of authorised GM food and feed, and will assist applicants in the generation, analysis and interpretation of the dataset that will be submitted as part of renewal applications. This initiative was undertaken as part of a self-task activity.

In line with EFSA's policy on openness and transparency and in order for EFSA to receive comments from the scientific community and all stakeholders, EFSA has launched a public consultation on the draft Guidance Document.

Interested parties are invited to submit written comments by 4 January 2015. Please exclusively use the electronic template provided with the documents to submit comments and refer to the line and page numbers. Please note that comments submitted by e-mail or by post cannot be taken into account and that a submission will not be considered if it is:

- submitted after the deadline set out in the call,
- presented in any form other than what is provided for in the instructions and template,
- not related to the contents of the document,
- contains complaints against institutions, personal accusations, irrelevant or offensive statements or material,
- is related to policy which is out of the scope of EFSA's activity.

EFSA will assess all relevant comments from interested parties which are submitted in line with the criteria above. The comments will be further considered by the EFSA GMO Panel and taken into consideration if found to be relevant.

All comments submitted will be published. Comments submitted by individuals in a personal capacity will be presented anonymously. Comments submitted formally on behalf of an organisation will appear with the name of the organisation.

Appendix B. Table of public comments

Table 1 lists the Member States' and stakeholders' comments received during the public consultation on the draft guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003.

Organization	Country	Chapter	Comments
Ministry of Agriculture	HUN	1. Abstract	Line 14: In the opinion of the Hungarian Authority all scientific publications must be presented. To preserve independency and transparency, the literature should not be evaluated by the applicants but by the risk assessors.
Ministry of Agriculture, Livestock and Fisheries of Argentina	ARG	1. Abstract	<p>Argentina wishes to express its concern regarding the regime on genetically modified food and feed and, particularly, on the period of validity set for GMO event's authorizations as well as the renewal requirement after a 10-year period without new scientific evidence justifying that requirement.</p> <p>The applicant of the authorization is obliged, and any person enabled, to submit at any time new scientific evidence requiring the revision of the authorization granted, making the 10-year period no sense.</p> <p>By the other hand, there are neither risk hypotheses nor precedents that justify an expiration and renewal system. In fact, in many cases these products will be cheaper and its safety and familiarity reassured by at least 10 years of consumption. In that regard, its market exit and subsequent replacement by new products no necessarily represents and advantage for the European consumer.</p> <p>In fact, and according to the Regulation N° 1829/2003 recitals themselves, it has been established a procedure with the aim of guaranteeing that the GMO authorizations are carried out considering a high level of protection of human life and health. In that regard, and being those authorizations a result of risk assessments developed by the EFSA, their revision should take place only in cases where new scientific evidence has arisen, a not based in the simple fact that a specific and arbitrary period of time has expired.</p> <p>It is important to highlight that if the EU revokes a GMO authorization because of the simple expiration of a time period, that decision would be inconsistent with the basic principles of the Agreement on the Application of Sanitary and Phytosanitary measures of the World Trade Organization (WTO), as for example, the obligation to base sanitary and phytosanitary measures on scientific evidence and apply them only to the extent necessary to protect human/animal/plant life or health.</p> <p>That is the reason why we would like to reiterate the European authorities (as we have previously done</p>

			<p>within the scope of the Bilateral Dialogue between Argentina and the EU on Biotechnology) that there is no scientific evidence supporting the existence of a limited period of time concerning the validity of a GMO authorization. This expiration clause, as well as any provision which unnecessarily difficult the renewal, will only worsen the asynchrony in the approvals between Argentina and the EU, situation which then led to the establishment of a Panel in the WTO.</p> <p>Secondly, we would like to highlight the complexity of analyzing the appropriateness of the requirements included in an authorization renewal procedure. In general terms, such a procedure should not constitute a barrier for a product's remaining in the market, specially when in many cases the intellectual property rights are close to expire, losing the original applicants their interest in the product's remaining in the market as a generic competence to their new developments. In contrast, those interested in the use of those products would be farmers and small national seed industries in developing countries, with less capacity to go through a regulatory process comparing to the original applicant.</p> <p>To sum up, Argentina considers that the whole renewal procedure has no scientific support, and distorts free and fair trade of seeds and food. Nevertheless, we kindly ask the European authorities to take into account the specific comments provided which explain in detail the most concerning aspects.</p>
Federal Office of Consumer Protection and Food Safety (BVL)	DEU	1. Abstract	<p>Line 14 (see also line 28) EFSA should specify in more detail what is meant by "any additional documents".</p>
GM Freeze, EcoNexus, ENSSER, FoE Europe, the Soil Association	GBR	1. Abstract	<p>Abstract – 2,294 characters</p> <p>PLEASE NOTE re submitting organisations: In all submissions from GM Freeze, EcoNexus, ENSSER, FoE Europe, the Soil Association, the following abbreviations are used:</p> <p>ENSSER = European Network of Scientists for Social and Environmental Responsibility FoE Europe = Friends of the Earth Europe</p> <p>Also, the country designation UK has been chosen because GM Freeze, EcoNexus and the Soil Association are in the UK, but both ENSSER and FoE Europe are Europe-wide organisations.</p> <p>* * *</p>

			<p>PAGE 1, LINE 16-18</p> <p>“The applicants should also make a proposal, if appropriate, for amending or complementing the conditions of the original authorisation, inter alia the conditions concerning future monitoring”. We recommend that this statement is removed.</p> <p>It is not appropriate for applicants to suggest amendments to conditions or future monitoring – that is a job for regulators and politicians, with public involvement. Applicants, wider industry interests and the public can then comment on any proposals.</p> <p>The record of industry to date is that they have not responded to EFSA-suggested improvements to Post Market Environmental Monitoring and have chosen instead to develop their own approach. It is extremely likely that if they did make proposals they would be aimed at protecting their shareholders rather than the environment, human and animal health.</p> <p>WHOLE ABSTRACT</p> <p>We also strongly recommend that the abstract provides a reminder of why the GMO Regulations exist. GMOs are the product of a technical intervention unlike conventional plant breeding. That intervention can produce unexpected and unintended changes to the composition of plants as well as the intended ones associated with the GM trait/s and the process of inserting genetic sequences. Applicants should be reminded that the whole organism should be assessed for direct and indirect negative impacts and risks rather than just for the intended changes produced by the genetic modification event.</p> <p>We also urge the inclusion of data and assessments that address the impacts of growing and producing imported crops on the environment, human health, food security and livelihoods (socio economic impacts) in the country of export. This is of crucial importance to consumers as well as for the ethical standards and extraterritorial obligations of Europe.</p>
ANSES - French Agency for Food, Environmental and Occupational Health & Safety	FRA	1. Abstract	<p>Line 8 : add "(GM)" after "No 1829/2003 on genetically modified" (proposed final version : "No 1829/2003 on genetically modified (GM) food...").</p> <p>Line 10 : remove "that" in the sentence "... the renewal of authorisations of that GM food...".</p> <p>Line 12 : is the plural form "event(s)" correct ? It raises the question of whether the applicant will have to submit 1 renewal application for each initial authorisation or if it will be possible for him to group various authorised transformation events in 1 renewal application.</p>

ANSES - French Agency for Food, Environmental and Occupational Health & Safety	FRA	1. Abstract	<p>KEY WORDS :</p> <p>Line 22 : add "(6)" twice, after "Articles 11" and "23" (proposed final version : "Articles 11(6) and 23(6)").</p>
EuropaBio	BEL	1. Abstract	<p>EuropaBio would like to reiterate that all products subject to an application for renewal have been approved for commercialisation on the EU market after being risk assessed as safe according to the EU legislation and the EFSA guidance documents as well as by other regulatory authorities. Furthermore, such products have been on the EU market for a period of 9+ years (duration of consent) with no reported adverse effects as it is detailed in the annual monitoring reports. The lack of adverse effects during the commercialisation period of the product confirms that the original risk assessment was correct in terms of safety. Therefore, the renewal of approval for such products should be in line with the above and not trigger a new risk assessment under these conditions.</p> <p>Lines 11-15: “the mandatory requirements for renewal applications, which should contain the identification of the transformation event(s), a copy of the authorisation, post-market monitoring and post-market environmental monitoring reports, systematic search and evaluation of literature, updated bioinformatics and any additional documents or studies on the GM food and feed”</p> <p>Replace with: “the requirements for renewal applications, which shall contain the information specified in Articles 11(2) and 23(2) of Regulation (EC) No 1829/2003: a copy of the authorisation, a report of the results of the monitoring and any other new information which has become available with regard to the evaluation of the safety in use of the GM food and feed and the risks of the GM food or feed to the consumer, animals or the environment, and where appropriate a proposal for amending or completing the conditions of the original authorisation”</p> <p>Justification: The particulars and documents that shall accompany an application for renewal of authorisation are defined by Regulation (EC) No 1829/2003. The guidance document cannot require information which goes beyond the boundaries of what is mandated by law.</p> <p>Lines 15-16: “Applicants are requested to assess the collected information and conclude whether the assumptions made during the previous risk assessment remain valid”</p>

			<p>Replace with: “Applicants should assess whether the collected information affects the validity of the conclusions drawn during the original safety assessment and as presented in the EFSA Opinion for the authorised product.”</p> <p>Justification: The conclusions of the original safety assessment are not based on mere assumptions but rather on robust scientific evidence as summarized and presented in the EFSA Opinion which is the basis for the European Commission to issue an authorisation. Note that the EFSA issued the original opinion after it verified (see Articles 6(3)(a) and 18(3)(a) of Regulation (EC) No. 1829/2003) that the food or feed complied with Articles 4(1) and 16(1) of Regulation (EC) No. 1829/2003.</p>
Ministry of Agriculture	HUN	2. Summary	Line 28: To preserve independency and transparency, the collected literature should not be evaluated by the applicants.
USDA	USA	2. Summary	<p>The United States appreciates the opportunity to comment on the European Food Safety Authority’s (EFSA) “Draft Guidance for Renewal Applications of Genetically Modified Food and Feed authorized under Regulation (EC) N. 1829/2003.”</p> <p>General Comments:</p> <p>The United States prefers not to use the term "genetically modified" or “GMO” because these terms can refer to both genetically engineered organisms (plants, microorganisms, animals) as well as those developed through conventional breeding techniques. Rather, the United States typically uses terms such as "genetically engineered "(GE) or "bioengineered."</p>

Umweltbundesamt (Environment Agency Austria) on behalf of the Ministry of Health	AUT	2. Summary	<p>General comments to the whole document/continued</p> <p>Updated data</p> <p>The current Guidance Document for renewal of authorisations of existing GMO products requires an updated molecular characterisation as well as updated information on expression and composition etc. (EFSA 2006, p.3). The draft guidance at hand though does not require the applicant to submit any updates of data submitted in the original application apart from the identification of the transformation event (point 2.1) and updated bioinformatics (point 2.4.2) (EFSA 2014). According to the draft guidance document sub-mission of new studies in accordance with current legislations and guidance is only required for newly identified hazards or uncertainties (EFSA 2014, p.9, line 232).</p> <p>However since the introduction of Regulation (EC) No 1829/2003 relevant new EFSA Guidance Documents (EFSA 2010, EFSA 2011, EFSA 2011a, EFSA 2011b) as well as an implementing Regulation (EC) No 503/2013 have become available. It is paramount that all authorisations granted in the EU are in accordance with the established current standards for risk /safety assessment. In order to guarantee this, renewal applications should include updated elements of those parts of the original application which are not yet in line with the standards set by EFSA and the EC. In particular the scientific requirements for the risk assessment of GM food and feed specified in Annex II of Regulation (EC) No 503/2013 should be fulfilled by renewal applications. A respective paragraph should be added to the draft guidance in chapter 1., 'Introduction' or chapter 2 'mandatory data requirements' to clarify that updated data have to be submitted in the renewal application if appropriate.</p> <p>EFSA (2006): Guidance Document of the Scientific Panel on Genetically Modified Organisms for renewal of authorisations of existing GNO products lawfully placed on the market, notified according to Articles 8 and 20 of Regulation (EC) No 1829/2003, The EFSA Journal (2006) 435, 1-4</p> <p>EFSA (2010): Scientific Opinion on Statistical considerations for the safety evaluation of GMOs. The EFSA journal, 8(1):1250. [59 pp.]. doi:10.2903/j.efsa.2010.1250</p> <p>EFSA (2011): Scientific Opinion on Guidance for risk assessment for food and feed from genetically modified plants. EFSA Journal 2011; 9(5):1250 [37pp.] doi:10.2903/J.efsa.2011.2150.</p> <p>EFSA (2011a): Guidance Document on Selection of Comparators for the Risk Assessment of GM Plants. EFSA Journal 2011; 9(5):2149. [21 pp.] doi:10.2903/j.efsa.2011.2149.</p> <p>EFSA (2011b): Guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants. EFSA Journal 2011; 9(8): 2316. [40 pp.] doi:10.2903/j.efsa.2011.2316.</p> <p>EFSA GMO Panel (2014): Draft Guidance for Renewal Applications of Genetically Modified Food and Feed authorised under Regulation (EC) No 1829/2003.</p> <p>http://www.efsa.europa.eu/en/consultations/call/141104.pdf</p>
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GM Freeze, EcoNexus, ENSSER, FoE Europe, the Soil Association	GBR	2. Summary	<p>Summary</p> <p>PAGE 2, LINE 30-32: “If appropriate, the applicants should also make a proposal, for amending or complementing the conditions of the original authorisation, inter alia the conditions concerning future monitoring”. We strongly recommend that this statement is removed.</p> <p>It is not appropriate for applicants to suggest amendments to conditions or future monitoring – that is a task for regulators and politicians. Applicants, wider industry interests and the public can then comment on any proposals</p> <p>The record of industry to date is that they have not responded to EFSA-suggested improvements to Post Market Environmental Monitoring and have chosen instead to develop their own approach. It is extremely likely that if they did make proposals they would be aimed at protecting their shareholders rather than the environment, human and animal health.</p>
ANSES - French Agency for Food, Environmental and Occupational Health & Safety	FRA	2. Summary	<p>Line 26 : same comment as on line 12 of the Abstract about the plural form "event(s)".</p> <p>Lines 29 and 30 : add "by the applicant" in the sentence "The collected information should be assessed to see..." (proposed final version : "The collected information should be assessed by the applicant to see..."), so there is no ambiguity that the applicant has to do so, and as a consequence "applicants" should be replaced by the singular form "applicant" in the following sentence "If appropriate, the applicants should..." (proposed final version : "If appropriate, the applicant should...").</p>
EuropaBio	BEL	2. Summary	<p>Header Page 2 onwards: “Risk assessment”</p> <p>Replace with: “Guidance for Renewal Applications of GM Food and Feed authorised under Regulation (EC) No 1829/2003” on all pages.</p> <p>Justification: Header needs to be corrected to reflect the title of the guidance document.</p> <p>Line 25: “This Guidance document describes the mandatory requirements for”</p> <p>Replace with: “This document provides applicants with guidance for the preparation of”</p> <p>Justification: The intended purpose of the document should be in line with Articles 11(6) and 23(6) of Regulation (EC) No 1829/2003 which is to provide “guidance” and not to change the mandatory legal thresholds applicable to applicants and EFSA.</p>

			<p>Lines 25-29: “the identification of the transformation event(s), a copy of the authorisation, post-market monitoring and post-market environmental monitoring reports, systematic search and evaluation of literature, updated bioinformatics and any additional documents or studies on the GM food and feed”</p> <p>Replace with: “a copy of the authorisation, a report of the results of the monitoring and any other new information which has become available with regard to the evaluation of the safety in use of the GM food and feed and the risks of the GM food or feed to the consumer, animals or the environment, and where appropriate a proposal for amending or completing the conditions of the original authorization.”</p> <p>Justification: The particulars and documents that shall accompany an application for renewal of authorisation are defined by Articles 11(2) and 23(2) of Regulation (EC) No 1829/2003. The guidance document cannot require information which goes beyond the boundaries of what is mandated by law.</p> <p>Lines 29-30: “The collected information should be assessed to see whether the assumptions made during the previous risk assessment remain valid”</p> <p>Replace with: “Applicants should assess whether the collected information affects the validity of the conclusions made during the original safety assessment and as presented in the EFSA Opinion for the authorised product.”</p> <p>Justification: The conclusions of the initial risk assessment are not based on mere assumptions but rather on robust scientific evidence as summarized and presented in the EFSA Opinion which was the basis for the European Commission to issue an authorisation. Note that the EFSA can only issue a positive opinion after it has verified (see Articles 6(3)(a) and 18(3)(a) of Regulation (EC) No. 1829/2003) that the food or feed complies with Articles 4(1) and 16(1) of Regulation (EC) No. 1829/2003. Emphasis of the applicant’s responsibilities is also consistent with Articles 11(2)(d) and 23(2)(d).</p>
Ministry of Agriculture	HUN	3. Background as provided by EFSA	<p>Lines 66-69: Since the new Guidance Document on the risk assessment of renewal applications of GM food and feed should consider the highest scientific standards and up-to-date data requirements, and since in 2003 – 2012 the data requirement for an application for authorization did not include a 90 day toxicology/feeding study, those data should now be supplied as part of the renewal applications.</p> <p>With the introduction of GM plants with herbicide resistant trait(s) higher concentrations of that total herbicide(s) than envisaged/permitted by their original authorisation applied to crops routinely. As a result the allowable herbicide residue levels had been increased several times since their authorization. Therefore, measuring the herbicide residue levels in each shipment of GM crops with a herbicide tolerant trait(s) should be made compulsory.</p>

GM Freeze, EcoNexus, ENSSER, FoE Europe, the Soil Association	GBR	3. Background as provided by EFSA	<p>Background as provided by EFSA</p> <p>The draft guidance provides the background to the legal aspects of GM food and feed application renewals but fails to remind applicants that the regulations governing the marketing of GM food and feed were introduced to protect public health, animal health, biodiversity and the environment. We recommend that these basic facts are reiterated in the background.</p>
ANSES - French Agency for Food, Environmental and Occupational Health & Safety	FRA	3. Background as provided by EFSA	<p>Line 62 : does the term "directly" means that this new Guidance document only applies to products authorised according to Articles 7 and 19 of Regulation (EC) No 1829/2003 and does not apply to the GM products for food and feed uses notified according to Articles 8 and 20 of this Regulation ("existing products") ? Will the 2006 Guidance document (EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2006. Guidance document of the Scientific Panel on Genetically Modified Organisms for renewal of authorisations of existing GMO products lawfully placed on the market, notified according to Articles 8 and 20 of Regulation (EC) No 1829/2003. EFSA Journal 435, 1-4.) be invalidated and replaced by this new Guidance document or will it still apply to the so called "existing products" ?</p>
EuropaBio	BEL	3. Background as provided by EFSA	<p>Line 56: "should"</p> <p>Replace with: "shall"</p> <p>Justification: Articles 11(6) and 23(6) of Regulation (EC) No 1829/2003 have imposed on the EFSA to publish detailed guidance for renewal applications of GM food and feed.</p> <p>Lines 58-61: Delete.</p> <p>Justification: The information on the EFSA's 2006 guidance document for the renewal of authorisations of existing GM products according to Articles 8 and 20 of Regulation (EC) No 1829/2003 is outdated and not relevant.</p> <p>Lines 61-64: Delete.</p> <p>Justification: The sentence is a mere repetition of lines 55-58.</p> <p>Lines 66-67: "expected in 2016."</p> <p>Replace with: "expected by no later than 1 March 2015".</p>

			<p>Justification: The authorisation of the first product authorised under Regulation (EC) No 1829/2003 expires in March 2016 (see EU Register of authorised GMOs). According to articles 11(1) and 23(1) the authorisations shall be renewable on application by the authorisation holder “at the latest one year before the expiry date of the authorisation”. Therefore, the respective renewal application needs to be submitted on 1 March 2015 at the latest.</p> <p>Lines 67-69: “The new guidance document on the risk assessment of renewal applications of GM food and feed should consider the highest scientific standards and up-to-date data requirements for the risk assessment of GM food and feed as laid down in EFSA Guidance documents.”</p> <p>Delete sentence.</p> <p>Justification: The information requirements for renewal applications are laid down in Articles 11 and 23 of Regulation (EC) No. 1829/2003. The guidance document cannot require information which goes beyond the boundaries of what is mandated by law. The regulation does not require applicants to provide data for renewal applications which may be demanded by EFSA guidance documents for new applications but were not required at the time of the original safety assessment.</p> <p>Lines 72-73: “Risk assessment Guidance for Renewal Applications of Genetically Modified Food and Feed”</p> <p>Replace with: “Guidance document for the risk assessment of the renewal of GM plant products authorised under Regulation (EC) No 1829/2003.”</p> <p>Justification: The wording should be aligned with the title of the original mandate.</p>
ANSES - French Agency for Food, Environmental and Occupational Health & Safety	FRA	4.Terms of reference as provided by EFSA	<p>Lines 80 and 81 : the scope of this new Guidance document should be defined more precisely in order to clarify whether it invalidates and replaces the 2006 Guidance document (EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2006. Guidance document of the Scientific Panel on Genetically Modified Organisms for renewal of authorisations of existing GMO products lawfully placed on the market, notified according to Articles 8 and 20 of Regulation (EC) No 1829/2003. EFSA Journal 435, 1-4.) and covers all the GM food and feed products or if the products notified according to Articles 8 and 20 of Regulation (EC) No 1829/2003 ("existing products") are excluded (see also the comment on line 62 of the "Background as provided by EFSA" paragraph).</p>

Defra	GBR	5. Assessment	Whilst this is draft guidance on the renewal of authorisations for GM food and feed, and our responsibility is for the deliberate release of GMOs, Defra has an interest in understanding EFSA's rationale for requesting information in applications for renewal. We are particularly concerned that renewing authorisations is not seen as an opportunity to generate new data for risk assessment purposes without a scientifically defensible rationale to suggest that this is necessary.
EuropaBio	BEL	5. Assessment	Line 86: "Assessment" Replace with: "Information requirements for renewal application". Justification: "Assessment" does not really fit as overall heading for Sections 1 through 4, in particular because there is an additional Section 3 called Risk assessment.
German Federal Agency for Nature Conservation	DEU	5. Assessment	We appreciate the draft guidance document as a necessary tool to describe the mandatory requirements for renewal applications. Nevertheless, we are of the opinion that the guidance needs some amendments.
German Federal Agency for Nature Conservation	DEU	5. Assessment	We appreciate the draft guidance document as a necessary tool to describe the mandatory requirements for renewal applications. Nevertheless, we are of the opinion that the guidance needs some amendments.
National Institute of Public Health and the Environment	NLD	6. Introduction	According to article 11 and 23 of Regulation 1829/2003, the following information has to be supplied for each renewal application of GM food and feed (a) a copy of the authorization, (b) report on the results of monitoring, (c) any new information has become available with regard to the evaluation of the safety in use of the food/feed and the risk of the food/feed to animals, humans or the environment, and (d) where appropriate, a proposal for amending or complementing the conditions of the original authorization, inter alia the conditions concerning future monitoring. We notice that the mandatory data described in the EFSA Guidance for Renewal Applications of EFSA goes far beyond these legal requirements. Moreover, for many of the requirements no scientific rationale is given why these data are obligatory for a renewal that not does not have to be risk assessed again
GM Freeze, EcoNexus, ENSSER, FoE Europe, the Soil Association	GBR	6. Introduction	1. Introduction PAGE 6, LINES 101, 102: We recommend that point d) should be deleted for the reasons given in our comments on the abstract and summary. It is not appropriate for applicants who stand to gain from weaker conditions and less onerous monitoring requirements to play such a role in regulating their own GMO.

ANSES - French Agency for Food, Environmental and Occupational Health & Safety	FRA	6. Introduction	Line 110 : add "by the applicant" in the sentence "... data requirements that need to be assessed according..." (proposed final version : "... data requirements that need to be assessed by the applicant according...").
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EuropaBio	BEL	6. Introduction	<p>Line 99: “to animals, humans”</p> <p>Replace with: “to the consumer, animals”</p> <p>Justification: This accurately reflects the binding requirements of Articles 11(2)(c) and 23(2)(c) of Regulation (EC) No 1829/2003.</p> <p>Lines 104-106: “Additional requirements for renewal applications are detailed in Article 8 of the Commission Implementing Regulation (EU) No. 503/2013 where the specifics for the methods of detection, identification and quantification of GM food or feed are laid down.”</p> <p>Replace with: “In addition, for the sole purposes of application of Articles 11(2)(d) and 23(2)(d) of Regulation (EC) No 1829/2003, Article 8 of the Commission Implementing Regulation (EU) No. 503/2013 provides for the applicability of the requirements set out in Annex III to this Regulation for a) the methods of detection, identification and quantification of the transformation event and b) samples of food or feed and their control samples, and information as to the place where the reference material can be accessed.”</p> <p>Justification: Article 8 of the Commission Implementing Regulation (EU) No. 503/2013 does not provide for additional data requirements per se. It specifies that the requirements of Annex III to the Commission Implementing Regulation (EU) No. 503/2013 shall apply only where there is “a proposal for amending or complementing the conditions of the original authorisation, inter alia the conditions concerning future monitoring”.</p> <p>Lines 108-109: “This document provides guidance on data requirements and assessment of renewal applications of GM food and feed for import and processing in the European Union (EU).”</p> <p>Replace with: “This guidance document assists the applicants in the preparation of applications for the renewal of authorisations for placing on the market GM food and feed.”</p> <p>Justification: The purpose of this guidance document is limited by Articles 11(6) and 23(6) of Regulation (EC) No 1829/2003.</p>
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USDA	USA	7. Mandatory data requirements	<p>Specific Comments:</p> <p>Regarding Mandatory Data Requirements, Updated Bioinformatics under Section 2.4.2, the United States notes that the request for information is not specific, and does not indicate a scientific basis. Could EFSA please provide more specific guidance as to what is requested by with “analysis of inter and intra-species sequence similarities.” Could EFSA please explain how many species need to be compared and why?</p> <p>The United States thanks EFSA for its consideration of our comments.</p>
GM Freeze, EcoNexus, ENSSER, FoE Europe, the Soil Association	GBR	7. Mandatory data requirements	<p>2. Mandatory data requirements</p> <p>PART 1 OF 2</p> <p>The mandatory data required for the risk assessments of renewal applications for GM food and feed are the same as those required for an initial application. These have been challenged as being inadequate to establish the safety of GMOs and products based on GM crops on several grounds. The core criticism is that the approach adopted in the EU continues to be based on comparative risk assessment rather than a comprehensive risk assessment of the GMO. The last decade has produced huge progress in the understanding of genes, how they function and interact and how GM DNA and proteins can survive digestive systems:</p> <p>Genes and enzymes are multifunctional. [ref: Hodges J, June 2009. Foundations, Fallacies, and Assumptions of Science for Livestock in Development. UN IAEA-FAO International Symposium on Sustainable Improvement of Animal Production and Health]</p> <p>Genes are interdependent. [ref: Hodges, J 2009 as above]</p> <p>Genes overlap in function. [ref: Hodges, J 2009 as above]</p> <p>Information flows both to and from genes. [ref: Hodges, J 2009 as above]</p> <p>Switches can modify gene expression. [ref: Hodges, J 2009 as above]</p> <p>The genome is highly integrated, compact and efficient. [ref: Hodges, J 2009 as above]</p> <p>“Junk DNA” is a myth – it is now known that DNA which does not code for protein is important at many levels such as gene expression and regulation, for cell division and biological time-keeping (eg ageing) or in</p>

			<p>crossing-over processes of chromosomal recombination. [ref: Hodges, J 2009 as above]</p> <p>Epigenetics (altered gene expression – such as gene silencing – due to external influences including environmental stress, diet and lifestyle) plays an important role in heritable changes to gene expression. [ref: University of Chicago Press Journals, 20 May 2009. "Epigenetics: 100 reasons to change the way we think about genetics". Accessed at Science Daily, 25 September 2012]</p> <p>Unexpected outcomes of GM events do occur. [ref: Prescott VE, Campbell PM, Moore A, Mattes J, Rothenberg ME, Foster PS, Higgins TJV and Hogan SP, 2005. "Transgenic expression of bean α-Amylase inhibitor in peas results in altered structure and immunogenicity". Journal of Agricultural and Food Chemistry. 53(23): 9023 – 9030]</p> <p>GM DNA can survive the digestive system. [ref: Prescott VE, Campbell PM, Moore A, Mattes J, Rothenberg ME, Foster PS, Higgins TJV and Hogan SP, 2005. "Transgenic expression of bean α-Amylase inhibitor in peas results in altered structure and immunogenicity". Journal of Agricultural and Food Chemistry. 53(23): 9023 – 9030]</p>
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GM Freeze, EcoNexus, ENSSER, FoE Europe, the Soil Association	GBR	7. Mandatory data requirements	<p>2. Mandatory data requirements</p> <p>PART 2 OF 2</p> <p>Continuing our evidence that the last decade has produced huge progress in the understanding of genes, how they function and interact and how GM DNA and proteins can survive digestive systems:</p> <p>Micro RNAs can survive digestive systems, pass into the blood supply and potentially silence genes in the person or animal that consumed the food or feed. [ref: Zhang L, Hou D, Chen X, Li D, Zhu L, Zhang Y, Li J, Bian Z, Liang X, Cai X et al., 2012. “Exogenous plant MIR168a specifically targets mammalian LDLRAP1: evidence of cross-kingdom regulation by microRNA”. Cell Research 22, 107-126]</p> <p>There are compelling indications of horizontal gene transfer from GM food to gut organisms in humans. [ref: Zhang L, Hou D, Chen X, Li D, Zhu L, Zhang Y, Li J, Bian Z, Liang X, Cai X et al., 2012. “Exogenous plant MIR168a specifically targets mammalian LDLRAP1: evidence of cross-kingdom regulation by microRNA”. Cell Research 22, 107-126]</p> <p>The viral gene VI (with active domains overlapping with the Cauliflower Mosaic virus promoter sequence used in the majority of commercialised GM crops) was only identified as a potential health risk in 2012. It was first known to be in GM crops in 1980 but is not included in risk assessments by industry or regulators. [ref: Podevin N and du Jardin P, 2012. “Possible consequences of the overlap between the CaMV 35S promoter regions in plant transformation vectors used and the viral gene VI in transgenic plants”. GM Crops and Food 3: 1-5]</p> <p>To emphasise: It is a combination of the novel gene and the impact of the gene insertion and transformation process on the rest of the genome that makes a GM crop different from a non-GM crop and hence: re-appraisal of GMOs should be based on a comprehensive risk assessment including compositional and nutritional analysis, rather than a comparative risk assessment. This should be a requirement both for first time applications and for renewal applications.</p>
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ANSES - French Agency for Food, Environmental and Occupational Health & Safety	FRA	7. Mandatory data requirements	Line 114 : replace "of" by "to" in the sentence "Any deviation of the hereunder..."
Ministry of Agriculture	HUN	8. Identification of the transformation event(s)	Lines 131-135: The text “the data should be generated from a representative number of current varieties of GM plants from different geographical areas that typically export to the European Union” should specify the minimum number of varieties of GM plants, as well as the minimum number of locations. It is suggested that at least 5 varieties of GM plants originating from a minimum of 3 locations should be required. Lines 137-139: Similarly, a set number of the hybrids for analysis should also be specified.
Defra	GBR	8. Identification of the transformation event(s)	The title of this section suggests that the required data are to confirm that existing event-specific detection and identification methods will be effective. However, the first paragraph implies that these data are also to inform the risk assessment (as the most obvious approach for checking that GM events can be detected using existing methods, ‘cannot be used as evidence’). We do not consider that mandatory re sequencing of inserts and flanking regions of previously authorised GM crops can be justified scientifically. ‘Single nucleotide polymorphisms and insertions/ deletions’ are common in crop plant genomes and are not considered a safety issue.

Ministry of Agriculture, Livestock and Fisheries of Argentina	ARG	8. Identification of the transformation event(s)	<p>In this section it is required to perform a DNA sequencing of the event. This is a scientifically unjustified requirement, because:</p> <ul style="list-style-type: none"> o All DNA in all plants used as food can mutate anytime. There is nothing special about DNA in a GMO event to justify this: it is not more prone to mutation, neither mutations in these genes may entail a different or increased risk compared to other genes in food plants. o To confirm this is scientifically unjustified, it can be noted that –as a “monitoring” or “renewal” requisite– it is not requested by CODEX Alimentarius. o Such requirement actually implies a poor understanding of population/mutation dynamics and agriculture. Mutation arises as an isolated, random event, which very likely will not display selection advantage and will be counter selected by humans. A mutation happening in a single isolated agricultural plant somewhere cannot become dominant or frequent for major plant food unless selected purposely by humans. The inserted genes will surely maintain its sequence in the overwhelming majority of plants and in all varieties, especially if we consider the latter as lines whose genetic purity and phenotype is maintained by human activity generation after generation. Therefore, this requisite will lead the applicant to perform several sequencing analysis in many plants –perhaps discarding the very infrequent mutation from the dataset, if any- and just file the overwhelming majority of data where no mutation arises.
VIB	BEL	8. Identification of the transformation event(s)	<p>2.1. Identification of the transformation event(s)</p> <p>There is no justification for asking to completely re-sequence and re-evaluate the insert and its flanking sequences in different varieties carrying the event. Any alteration to the insert or its flanking sequence will be the result of natural processes (natural mutations, conventional cross breeding). Such processes and the organisms obtained through them have a safe history of use and are therefore not subject to the requirements of the GMO legislation. Therefore, from a legal and safety point of view, data requirements for renewal applications should be limited to phenomena caused by the genetic modification and should not include phenomena that are caused by natural processes. The data should be limited to showing that the event/varieties are still clearly identified with the available detection methods. This is to ensure that the legislation can continue to be correctly enforced after the renewal.</p>

Belgian Biosafety Advisory Council	BEL	8. Identification of the transformation event(s)	<p>The Guidance Document (GD) for Renewal Applications describes that a mandatory requirement for renewal applications, is the identification of the transformation event(s), meaning a re-sequencing of the insert DNA and insertion site of a representative number of current varieties per geographical area that export to the EU. The guidance document states “1 kb on each side of the insert is normally considered the minimum requirement”. We want to note that this is a new requirement, neither described in existing EFSA GDs, nor prescribed by international GDs, such as the OECD (OECD, 2010) , and thus is all but ‘a normal minimum requirement’.</p> <p>Since mutations indeed occur continuously in nature, we question why a GM event for renewal should be re-sequenced after 10 years. One can question why GM events should not be re-sequenced, for example, every 5 years or each time a new variant is placed on the market? A clear scientific rationale is lacking in the GD. We therefore wonder whether the re-sequencing data are asked to guarantee the safety of the GMO or rather to guarantee the detection of the GM event? We would like to have this clarified in the GD. If re-sequencing data are asked for risk assessment purposes, we would like to see a scientific explanation as to why DNA inserts need to be re-sequenced every 10 years and why the evaluation of the genetic stability, which is part of the risk assessment of every GM event placed on the market, is no longer seen as ‘sufficient’ to cover this issue.</p> <p>Further, we would like to see explained in the GD as to what is considered a ‘representative number of current varieties per geographical area’.</p> <p>Finally, we want to point out that mutations occur in plants during conventional breeding, whether they are genetically modified or not. We do not understand why one should focus on mutations only in the context of GM plants. If the phenotype demonstrates that the function of the insert is not comprised, risk assessment wise we would consider this information more informative than the sequence of the insert of several varieties.</p> <p>In conclusion, due to a lack of scientific rationale for re-sequencing data, we see no reason to ask for re-sequencing every 10 years in order to guaranty the safety of the GM event.</p>
Spanish National Commission on Biosafety	ESP	8. Identification of the transformation event(s)	<p>Regulation EC N° 1829/2003 establishes a set of data requirements for the renewal of the applications, but it does not include the sequencing of a “representative number of current varieties from different geographical areas that typically export to the EU”. We consider this requirement no only out of the legal provision, but disproportionate for the renewal of events that have been marketed in Europe for 10 years, and even longer out of Europe. When the Regulation says “identification of the event”, it refers to the method of identification accepted by the JRC, no to a new resequencing of the insert and flanking sequences.</p>

Spanish National Commission on Biosafety	ESP	8. Identification of the transformation event(s)	Regulation EC N° 1829/2003 establishes a set of data requirements for the renewal of the applications, but it does not include the sequencing of a “representative number of current varieties from different geographical areas that typically export to the EU”. We consider this requirement not only out of the legal provision, but also disproportionate for the renewal of events that have been marketed in Europe for 10 years, and even longer out of Europe. When the Regulation says “identification of the event”, it refers to the method of identification accepted by the JRC, not to a new resequencing of the insert and flanking sequences.
National Institute of Public Health and the Environment	NLD	8. Identification of the transformation event(s)	<p>We wonder why for the ‘identification of the transformation event’ the validated event-specific detection method does not seem to be sufficient for EFSA. EFSA states that the event, including 1 kb of flanking regions, has to be resequenced because mutations can occur in the insert, flanking sequences or both. Genetic changes have to be further considered and risk assessed. We like to point out that plant genomes are not fixed and mutations are likely to occur. Mutations like insertions, deletions and SNPs are common and not regarded as a risk. Moreover, such mutations will not change the identity of the transformation event. We therefore see no reason to request for resequencing data for a renewal.</p> <p>EFSA requests new sequence data of the flanking regions of 1 kb in order to provide an updated bioinformatics analysis. There does not seem to be a rationale to request for a length of 1 kb. Moreover, this is not standard requirement of EFSA. EFSA should explain why in the case of a renewal of an event that is already risk assessed, the required length of the flanking regions has to be extended for the purpose of bioinformatics analysis.</p> <p>Data should be generated from a ‘representative number of current varieties of GM plant from different geographical areas that typically export to the European Union Material used for sequencing’. We wonder why these data are required. Is it the assumption that the mutation frequency will differ in other backgrounds or in other geographical regions? Can EFSA explain why these data are necessary for the identity of the transformation event or is this just an academic requirement? And can EFSA explain how many plants/lots have to be sequenced per variety and what is ‘a representative number of varieties’?</p> <p>EFSA should explain why sequence data have to be collected for single events that are not or no longer commercialized</p>

JKI	DEU	8. Identification of the transformation event(s)	<p>It is correct that naturally occurring mutations cause genomes to evolve. Mutations do not only arise in the sequences specific to the GM event and its flanking areas but throughout the entire genome. During the ten years of planting, the genome of the GM plant has evolved as a whole. If the characteristics of the event have been maintained, and if no adverse effects have been detected, there is no reason to assume that the behavior of the plant has changed with respect to safety.</p> <p>Thus any mutation - be it within the GM specific sequences or somewhere else in the genome - is equally likely to be or be not a point for safety concerns.</p> <p>The demand for re-sequencing specific areas of the genome is creating a large work afford and large costs without any increase in risk specific data. One should ask, which would be the scientific as well as the regulatory consequences of detection of a single base pair mutation. And the same question applies to the detection of a mutation in one or another variety at one or another geographical area.</p> <p>In addition, how is it possible to demand collection of sequencing data from events that are not or no longer commercialized and thus are not subject of the application.</p> <p>Applicants are requested to explain the rationale applied for selecting the GM plant material. With even more seriousness should the EFSA explain the scientific rationale for these sequencing requirements.</p>
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Federal Office of Consumer Protection and Food Safety (BVL)	DEU	8. Identification of the transformation event(s)	<p>Line 117-135: The German CA likes to stress the point that an approval or risk assessment of events in specific varieties is not foreseen by EU legislation. An application and approval under Regulation (EC) No 1829/2003 refers to the event as such and not to the variety or event/variety combination. This principle should be retained for applications for renewal.</p> <p>From a biological point of view, it is important to note that all plant genomes are constantly changing in small ways, e.g. through errors in DNA replication or spontaneous lesions. Genetic changes occur in both, genetically modified as well as conventionally bred plants and, therefore, present a similar level of risk in both of them. This is because naturally occurring mutations in GM events have in general the same probability as in any other genes and, hence, pose a risk that is not different from mutations in endogenous genes. As there is a history of safe use in agriculture as well as food and feed produced from conventionally bred varieties and because subsequent genetic changes within a given variety are not specific to genetically modified plants, it is inappropriate to put an outsized focus on this specific issue only in the context of genetically modified plants. On these grounds, the necessity of generating sequence data "from a representative number of current varieties of GM plants from different geographical areas" is neither obvious nor mandatory.</p> <p>Furthermore, as mutations may occur at any time in any new production lot during the entire period of approval, there is no gain in safety by sequencing individual samples. These analyses cannot exclude mutational changes in other varieties or production lots. Beyond that EFSA just refers to "a representative number of current varieties of GM plants from different geographical areas". What is "a representative number of current varieties" in view of EFSA (how much is enough?). What is the scientific rationale to use plants "from different geographical areas"? Considering the fact that spontaneous mutations can occur at any time and any place in any plant, it is never possible to cover all feasible scenarios.</p> <p>In conclusion, the German CA is of the opinion that demonstrating sequence identity across different varieties carrying the event and originating from different geographical areas should not be a requirement and should be omitted from this guidance. In an application for renewal the event should be characterized once with all required bioinformatic information in the same way as was requested in primary applications.</p> <p>Line 137-138: Does the wording "Last generated" refer to the time of sequencing or the time of application? Suggestion: "For commercialized GM food and feed, sequence data should be collected from material produced recently before the time of application for renewal".</p>
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GM Freeze, EcoNexus, ENSSER, FoE Europe, the Soil Association	GBR	8. Identification of the transformation event(s)	<p>2.1. Identification of the transformation event(s) – 2798 characters</p> <p>We welcome the requirement for applicants to “confirm the identity of the event(s) for renewal authorisation by sequencing. In addition, the characterisation of the flanking sequences should provide updated sequence data for subsequent bioinformatic analyses”.</p> <p>We would strongly recommend that this should extend to genome-wide mutations which result from the original transformation process (including genetic sequence insertion processes and tissue culture) to ensure that they are identified, stable, have not given rise to and are not subject to, further mutations.</p> <p>The draft guidance does not specify the techniques that should be employed to confirm the identity of event and flanking sequences. We recommend that these should be specified to ensure the best possible data is available. A previous review found that Southern Blot analysis was insufficient to identify on-site mutations and proposed that PCR techniques and gene sequencing should also be used. [ref: Wilson A, Latham J and Steinbrecher R, (2006). “Transformation-induced Mutations in Transgenic Plants: Analysis and biosafety implications”. Biotechnology and Genetic Engineering Reviews, 23: 209-237]. The same review also reported that flanking mutations could be larger than the 1kbp each side of the insert (the largest reported were 40 and 78kbp). We therefore recommend that the requirement to test for mutations in flanking sequences should be increased substantially, ideally to more than the largest recorded in literature and research documents. This should be a requirement both for first time applications and for renewal applications, with the latter providing both data sets.</p> <p>PAGE 6, LINE 117: we suggest replacing “evolve” with “change”, as ‘evolve’ has connotations of better or improved, both of which are not appropriate for this section and purpose.</p> <p>PAGE 7, LINE 129: please insert “eg” or “such as” inside the bracket and add “translocations, inversions and amplifications” to the bracketed list. All forms of DNA changes (mutations) need to be carefully considered, not just those currently listed in the draft guidance.</p> <p>PAGE 7, LINE 132/3: The language here is currently not sufficient and lacks clarity. It should be amended to ensure that statistically significant numbers of samples are taken from ALL the various varieties of GM plants (containing only the event, ie not stacked). It must also require geographical representation of the various varieties in order to derive datasets that can indicate whether changes have taken place within varieties (eg across geographical areas) and across varieties – and to which extent.</p>
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			PAGE 7, LINE 134: Applicants should cover ALL the varieties that may be imported into the EU, but should justify the choice of geographical areas if not all are being covered.
National Food Institute	DNK	8. Identification of the transformation event(s)	<p>General comments:</p> <p>Articles 11(6) and 23(6) of Regulation (EC) No 1829/2003 read: "The authority shall publish detailed guidance to assist the applicant in the preparation and the presentation of its application." This guidance for renewal applications of GM food and feed should in our view focus on the case by case scientific experience obtained with the plant and plant products from the last 10 years including data from monitoring. Based on this information the need for further information, such as sequencing, expression analysis, monitoring etc. should be assessed. If the information do not indicate any new risk or uncertainties there are no scientific reasons not to consider the GMO as any other traditional bred organism.</p> <p>As scientific experts dealing with risk assessment of GMO for more than 25 years the current draft guidance seems more as management than guidance based on scientific principles and knowledge about GMO. Not a single reference or other kind of hints is included as scientific argument to justify the inquired information, e.g. requirement of flanking sequence based on what is "normally considered the minimum" is not a scientific justification and using mandatory (data) requirements in the guidance is not related to science. Other examples can be found under the specific comments. It is difficult to give scientific response to this draft guidance due to the lack of scientific arguments or explanations. We urge EFSA to be more open about the scientific background leading to this and other guidance and will propose EFSA to include external scientific experts to review the scientific content. One general question that should be of interest for both managers and scientist to put forward is how GMO is different from traditional breeding and whether all GMO should be treated in the same way from a risk point of view. This could be in relation to natural mutation, breeding, influence of the genomic background in different varieties, influence on the nature when growing different crops etc. This as well as the many years of experience from GMO seems unfortunately not to have influenced this guidance. EFSA is therefore requested to explain the scientific rationale applied for this very strict guidance where genetic engineering seems to be considered as being considerable more risky than other breeding techniques. This guidance follows other guidances from the EFSA GMO panel with the principle always to enhance the documentation requirements for GMO plants. There are, however, no science based reason to increase the data collection. That is in our view risk management, which is out of scope for EFSA GMO panel.</p>

National Food Institute	DNK	8. Identification of the transformation event(s)	<p>The requirement for re-sequencing is not scientifically explained and is not scientifically justified and therefore should be deleted from this guidance. There are no new insertion events and no new gene construction, so the requirement for re-sequencing is only regulation of naturally occurring mutation events. Mutations are outside the EU GMO-regulation. Furthermore the existing risk assessment from EFSA should already have taken into consideration the fact that mutation occur naturally and should be accepted as a naturally occurring event that are not specifically related to GMO's. It is difficult to see the usefulness of requiring a 1kb sequence in the plant part flanking the inserted construction. How will this information be used compared to other mutations that probably have occurred in the GMO plants or to risks related to the breeding that probably have occurred and involved introduction of the GM-trait into many varieties? The sentence stating that "1kb on each side of the insert is normally considered the minimum requirement..." is very vague in the sense that it is not clear where this is a "normal" requirement (at EFSA?) or clear how this requirement is related to requirement for renewals. It is stated that the sequences should be generated from single events at a representative number of varieties. If there are e.g. 45 varieties it is not clear how many should be analysed. If the single event is not used commercially, but only occurs in stacked events, how useful would it be to analyse the single event taken from a seed bank.</p> <p>If EU continues to require methods that can catch every event approved in EU, and that may seem reasonable, it is adequate to ask for documentation that the approved method is still working e.g. by showing positive results from different varieties with that event.</p>
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<p>ANSES - French Agency for Food, Environmental and Occupational Health & Safety</p>	<p>FRA</p>	<p>8. Identification of the transformation event(s)</p>	<p>Lines 116 to 118, line 122, line 128, line 132 : same comment as on line 12 of the Abstract and line 26 of the Summary about the plural form "event(s)". The singular form seems more adapted in this paragraph. Line 117 : add "and crosses used in the frame of germplasm conservation and/or seed production" in the sentence "Since naturally occurring mutations cause genomes to evolve..." (proposed final version : "Since naturally occurring mutations and crosses used in the frame of germplasm conservation and/or seed production cause genomes to evolve..."). Lines 122 and 123 : add "the insert(s)" after "... for renewal authorisation by sequencing" (proposed final version : "... for renewal authorisation by sequencing the insert(s)."). The term "insert(s)" should be written in the singular/plural form since a transformation event may contain several inserts (even if this is less and less the case in recently developed GM plants). Line 124 : replace "Unless the insertion site is..." by "Unless the insertion site(s) is (are)..." since a transformation event may contain several inserts (see also the comment on lines 122 and 123 of this paragraph). Line 126 : place "et al." in italics. Line 126 : replace "insert" by "insert(s)" in the sentence "... a length of 1kb on each side of the insert is normally..." (proposed final version : "... a length of 1kb on each side of the insert(s) is normally..."). Line 129 : replace "or" by "and/or" in the sentence "... (SNPs, insertions or deletions)...". Line 131 : add "DNA extraction and " in the sentence "... The material used for sequencing..." (proposed final version : "... The material used for DNA extraction and sequencing..."). Lines 137 to 141 : why make a difference between "commercialised GM food and feed" (line 137) and "single events that are not or no longer commercialised" (line 139) ? Lines 128 to 141 : proposal to put "In some cases, it may be necessary to extend the sequence analysis further into the plant genomic DNA (see Section 3)." after "... minimum requirement for the characterisation of flanking sequences." (line 127) and to write in a new paragraph "Sequence data should be collected from the latest grown generation, or from the last generated batch of homozygous parental lines for those crops typically marketed as hybrids (e.g. maize, oilseed rape). The material used for DNA extraction and sequencing should be selected from GM plants only containing the event for which renewal is sought. The data should be generated from a representative number of current varieties of GM plants from different geographical areas that typically export to the European Union. Applicants are requested to explain the choice of varieties, geographical areas and GM plant material. In case the sequence is not identical to the one of the initially authorised event, the genetic changes (SNPs, insertions and/or deletions) should be further considered, discussed and risk assessed (see Sections 2.4.2 and 3).".</p>
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EuropaBio	BEL	8. Identification of the transformation event(s)	<p>Delete the entire section 2.1.</p> <p>Justification: Articles 11 and 23 of Regulation (EC) No 1829/2003 do not require confirmation of the identity of the event as a requirement for a renewal application as acknowledged by EFSA (lines 93-102 of the draft guidance). The guidance cannot require information which goes beyond the boundaries of what is mandated by law in Articles 11(2)(c) and 23(2)(c), which indicate that “new information” is limited to what has already “become available” to the authorisation holder and does not have to be generated for the purpose of renewal.</p> <p>Genetic mutations on genomes naturally occur in all crops, including conventional varieties by breeding and/or natural recombination. These are not perceived as unsafe or assessed in respect of safety. In fact, the Regulation explicitly excludes from its scope alterations in genetic material occurring naturally by mating and/or natural recombination. Therefore, after the GMO product was originally assessed for safety it was approved without any restriction in terms of breeding into different genetic backgrounds (lines/varieties) and any (potential) consequent alterations at the DNA level (e.g. mutations), which are naturally occurring. This is applicable for (potential) alterations at the genome level as well as the insert level. There is no scientific evidence that the frequency of naturally occurring genetic mutation in the insert or flanking regions is any greater than for the rest of the plant genome (Weber (2012), Plant Physiology 160(4), 1842-1853 and Kok (2014), TIB 32(2), 70-73, Papazova (2010), Analytical Biochemistry, 396:2189-2201).</p> <p>Moreover, EFSA previously concluded that “since there is no evidence from the scientific literature indicating that small sequence changes should be analysed for the safety evaluation of a stacked event, the added value of this new requirement is unclear” (EFSA Journal 2013; 11(12)). Hence, the requirement as laid down in Section 2.1 is not in line with the Regulation and previous conclusions by EFSA. Any departure from past EFSA conclusions would need to be justified in detail.</p> <p>Besides lacking scientific and legal rationale for such a requirement, the document remains unclear which lines should be sequenced, what a representative number of current crop varieties would be, how to conduct a scientifically valid comparison with the original sequence, and how EFSA would be able to interpret such data, e.g. if a SNP occurred in one but not in other varieties. This creates a fundamental problem of legal certainty. Applicants for renewals would be unable to determine the standards which they are expected to satisfy. These must be clear and understandable and ambiguities must be resolved in favour of the applicant (Case C-169/80, Gondrand and Garancici).</p> <p>Single base mutations are a natural occurrence and it is possible that a SNP may occur in a GM event and</p>
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			<p>that this germ line may subsequently be used to generate a localized population that would not be identified through the renewal process. This occurrence would be exceedingly rare and no more likely to happen in a GM event than in any other gene.</p> <p>The sequencing and analysis of a larger “representative” selection of genetic backgrounds, with a given GM event, would be unlikely to identify a SNP in a GM event while at the same time completely ignoring the very likely development of SNPs in endogenous genes.</p> <p>Furthermore, the draft guidance states that material used for sequencing should be selected from GM plants only containing the event(s) for which renewal is sought. This would be a challenge for single events, since these are typically not commercialized. Usually, commercialized products have multiple traits incorporated in the form of higher order stacks.</p>
German Federal Agency for Nature Conservation	DEU	8. Identification of the transformation event(s)	<p>Line 118-121 It should also be validated that the method provided in the original application is still adequate to detect the specific GMO.</p> <p>Line 129: The brackets only contain examples of possible genetic changes that might have occurred over time. Thus, “e.g.” should be added.</p>
German Federal Agency for Nature Conservation	DEU	8. Identification of the transformation event(s)	<p>Line 118-121 It should also be validated that the method provided in the original application is still adequate to detect the specific GMO.</p> <p>Line 129: The brackets only contain examples of possible genetic changes that might have occurred over time. Thus, “e.g.” should be added.</p>
Ministry of Agriculture	HUN	10. Post-market monitoring and post-market environmental monitoring reports	<p>Lines 146-148: Even when a GM crop is not cultivated and grown in the EU, a PMEM performed outside the EU should be submitted with the renewal application.</p> <p>Lines 146-151: If and when resistance to any introduced trait had developed anywhere, those data must be reported as part of PMEM.</p>

Ministry of Agriculture, Livestock and Fisheries of Argentina	ARG	10. Post-market monitoring and post-market environmental monitoring reports	<p>Again this is an unnecessary requisite that would become a barrier for a third party wishing to file a renewal application. If the original applicant is not interested in keeping the product in the market –since it may be in the public domain already or about to– likely neither it will be interested in sharing the Post Market Monitoring report with that third party.</p> <p>If the post Market Monitoring shows in any moment during the 10-year period that there is new information affecting the authorization decision, the original applicant must report this immediately to the European authorities, so it is not reasonable to lay this draft guidance presuming such information was not available before. In contrast, if the rationale is that the original applicant may be hiding or interpreting some information differently from the authorities, then the original applicant should be required to forcedly submit the report after the 10-year period anyway, regardless of the fact that a renewal application has been filed or not. Additionally, it is worth recalling that according to the Regulation 1829/2003 “The authorisation-holder shall forthwith inform the Commission of any new scientific or technical information which might influence the evaluation of the safety in use of the feed”. That would make not necessary to require the inclusion of this documentation since it is already available to the European authorities, and in this way the third party would not be excluded by a technicality.</p>
Belgian Biosafety Advisory Council	BEL	10. Post-market monitoring and post-market environmental monitoring reports	<p>It is not clear to us why PMEM reports are requested in this GD, as this GD only applies to renewal applications of GM food/feed for import and processing.</p> <p>Further, it is not clear from the GD if the report(s) requested for renewal are just the report(s) covering year 9 to 10, or all the reports provided over de last 10 years. To our opinion, the monitoring report(s) requested for a renewal application could just be the one(s) applicants hand in every year.</p>
GM Freeze, EcoNexus, ENSSER, FoE Europe, the Soil Association	GBR	10. Post-market monitoring and post-market environmental monitoring reports	<p>2.3. Post-market monitoring and post-market environmental monitoring reports – 2,502 characters</p> <p>PART 1 OF 2</p> <p>Post Market Monitoring (PMM) and Post Market Environmental Monitoring (PMEM) by consent holders are unproven methods of ensuring that the assumptions in the original risk assessment were correct and that unexpected changes have been identified.</p> <p>1) Significant changes such as weed and pest resistance may take many years to evolve. Glyphosate resistance in weed species was confirmed to occur in the USA 4 years after commercial growing started and in Argentina after 7 years [ref: Heap, I. The International Survey of Herbicide Resistant Weeds. Online. Internet. Thursday, December 11, 2014. Available at www.weedscience.org]. In India, Monsanto confirmed Bt-resistant pests in GM cotton in 2010, 8 years after the first commercial crop. [ref: Sharma, D, 2010. Bt Cotton Has Failed Admits Monsanto. India Today, 6th March 2010. Available at</p>

			<p>http://indiatoday.intoday.in/site/Story/86939/India/Bt+cotton+has+failed+admits+Monsanto.html]</p> <p>2) EFSA itself has expressed concerns about methodology used in PMEM of MON810: “However, having already highlighted the poor sensitivity of the methodology followed by the applicant, the EFSA GMO Panel strongly reiterates its previous recommendations for the improvement of the methodology”. [ref: Monsanto Europe, 2013. Annual monitoring report on the cultivation of MON810 in 2012 Czech Republic, Portugal, Romania, Slovakia, and Spain. Available at http://ec.europa.eu/food/plant/gmo/reports_studies/docs/report_2012_mon_810/report_2012_mon_810_en.pdf]</p> <p>3) A questionnaire sent to farmers growing GM crops may detect agronomic change over 10 years but is not designed to detect potentially significant indirect effects such as hybridisation with wild relatives, reduced activity of pollinators or other effects on non-target species in the surrounding area. Surveys of livestock farmers feeding MON810 maize to pigs or chickens have not been carried out as part of their PMEM programme.</p> <p>4) Tenders for “Strategy Support for the Post Market Monitoring (PMM) of GM plants: Review of existing PMM strategies developed for the safety assessment of human and animal health (OC/EFSA/GMO/2013/03)” were invited in 2013. It is therefore unlikely that data has been evaluated so far and this re-enforces our view that PMM will provide limited information for re-approval applications at present. To be of value in the future PMM should be carried out independently and should be based on sample sizes which are capable of detecting significant changes in three years.</p>
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GM Freeze, EcoNexus, ENSSER, FoE Europe, the Soil Association	GBR	10. Post-market monitoring and post-market environmental monitoring reports	<p>2.3. Post-market monitoring and post-market environmental monitoring reports – 2,001 characters</p> <p>PART 2 OF 2</p> <p>Thus far no specific attempts have been made to monitor farm animal health for effects of consuming MON810 maize. Monsanto has ignored EFSA’s recommendations on improving general surveillance:</p> <p>Monsanto acknowledges the fact that EFSA made several recommendations to improve the methodology on how to perform General Surveillance, i.e., in their general guidance document for post-market environmental monitoring (PMEM) of GM crops in August 2011 (EFSA, 20116) and two specific opinions on MON810 monitoring in the 2009 and 2010 growing seasons (EFSA, 20117; 20128). However, Monsanto chose to pursue its gained expertise on MON 810 monitoring and already established methodologies in order to report on the results for the 2012 growing season, and this decision has been taken for several reasons. Firstly, as said before, General Surveillance monitoring for MON810 cultivation is conducted by Monsanto on a voluntary basis. Currently, the consent allowing MON810 cultivation in the EU does not contain obligatory General Surveillance monitoring conditions (Commission Decision 98/294/EC). As long as no authorization decision has been reached on the MON810 renewal application (pending since 2007) containing General Surveillance monitoring as a condition of the consent, Monsanto elects to continue its current modus operandi. [ref: Monsanto Europe, 2013. Annual monitoring report on the cultivation of MON810 in 2012 Czech Republic, Portugal, Romania, Slovakia, and Spain. Available at http://ec.europa.eu/food/plant/gmo/reports_studies/docs/report_2012_mon_810/report_2012_mon_810_en.pdf</p> <p>PAGE 7 LINE 160: add “and PMM” at end of sentence. Also add a new sentence requiring companies to list any feeding trials that have been carried out with the GM event since first approval, including published and non-published company (and company financed) trials as well as trials conducted by third parties.</p> <p>This point is also relevant to be added at line 175 (as submitted under section 2.4.1)</p>
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ANSES - French Agency for Food, Environmental and Occupational Health & Safety	FRA	10. Post-market monitoring and post-market environmental monitoring reports	<p>Line 158, after "(see Section 3)", add : "Based on the information collected during the PMM, the applicant shall review the nutritional and safety assessments conducted as part of the initial risk assessment. This will include a risk assessment of toxicological effects and/or metabolic modifications, based on an analysis of the relevant scientific literature and/or on complementary studies".</p> <p>Lines 159 and 160 : replace "impacts" by "effects" in the sentence "... exposure and adverse impacts observed..." (proposed final version : "... exposure and adverse effects observed...") and add "and the PMM" after "... during the PMEM" (proposed final version : "... during the PMEM and the PMM.").</p> <p>After line 160, add the following paragraph : "For the GMO products notified according to Articles 8 and 20 of Regulation (EC) No 1829/2003 ("existing products") that were authorised without a repeated-dose 90-day oral toxicity study in rodents on whole food/feed, the applicant will have to propose and implement a PMM".</p>
EuropaBio	BEL	10. Post-market monitoring and post-market environmental monitoring reports	<p>Lines 146-151: "Following the placing..."</p> <p>Replace with: "Following the placing on the market of the GM food and feed in the EU and where post-market monitoring as referred to in Articles 5(3)(k) and 17(3)(k) and/or monitoring as referred to in Article 5(5)(b) and 17(5)(b) has been imposed as a condition of the authorisation, the authorisation holder shall implement the post-market monitoring plan(s) and submit reports to the European Commission according to the conditions specified therein. Authorisation holders are requested to report on the post-market monitoring for environmental effects in accordance with the standard reporting formats established by the European Commission Decision 2009/770/EC."</p> <p>Justification: This accurately reflects the binding requirements of Regulation (EC) No 1829/2003.</p> <p>Lines 153-155: "According to Articles 11 and 23 of Regulation (EC) No 1829/2003, the PMEM and, whenever available, PMM reports should be provided by applicants to support the assessment of renewal applications."</p> <p>Replace with: "According to Articles 11 and 23 of Regulation (EC) No 1829/2003, a report on the results of the monitoring, if so specified in the authorisation, should be provided by applicants to support the assessment of renewal applications."</p> <p>Justification: The wording needs to accurately reflect the binding requirements of Articles 11 and 23. Only monitoring reports as specified in the original authorisation will have been generated and submitted to the European Commission throughout the authorisation period.</p> <p>Line 157: "require"</p>

			<p>Replace with: “suggest”</p> <p>Justification: The outcome of the evaluation of the results of the post-market monitoring following the initial placing on the market of the GM food and feed may not necessarily compel stricter risk management or monitoring measures but potentially may also suggest a simplification thereof. In accordance with Articles 11(2)(d) and 23(2)(d) of Regulation (EC) No 1829/2003, where appropriate, the application shall be accompanied by a proposal for amending or complementing the conditions of the original authorisation, inter alia the conditions concerning future monitoring. It is not appropriate or legally accurate for the guidance to pre-judge the nature of any such modifications.</p> <p>Lines 159-160: “Applicants need to describe any unintended environmental exposure and adverse impacts observed during the PMEM”</p> <p>Delete sentence.</p> <p>Justification: The sentence is redundant in view of the previous sentence which states that it needs to be assessed whether the results of PMEM change the conclusions of the original risk assessment. Furthermore, the PMEM reporting format already provides for what needs to be observed and reported on. Any adverse impacts, if observed, would need to be reported immediately as per Articles 9(3) and 21(3) of Regulation (EC) No 1829/2003.</p>
German Federal Agency for Nature Conservation	DEU	10. Post-market monitoring and post-market environmental monitoring reports	<p>Please add:</p> <p>Applicants should consider and evaluate the efficiency of the monitoring methods, which were applied during the period of consent in order to identify important surveillance gaps and methodological shortcomings. Applicants should explain how they will fill the identified gaps within the PMEM.</p>
German Federal Agency for Nature Conservation	DEU	10. Post-market monitoring and post-market environmental monitoring reports	<p>Please add:</p> <p>Applicants should consider and evaluate the efficiency of the monitoring methods, which were applied during the period of consent in order to identify important surveillance gaps and methodological shortcomings. Applicants should explain how they will fill the identified gaps within the PMEM.</p>

Ministry of Agriculture, Livestock and Fisheries of Argentina	ARG	11. New information	<p>We would like to take this opportunity to ask the European authorities the rational behind being only the original applicant the one who can request the GMO authorization renewal. This requisite impede without justification that any other interested part could provide the necessary information to renew the authorization, limiting this right to the original applicant. Consequently, if the original applicant has no interest in renewing the GMO authorization, it expires due to merely private reasons, without scientific justification, causing unnecessary disruptions to international trade.</p> <p>Secondly, and taking into account that the objective of the guidelines developed by EFSA should be helping the applicant in the preparation and presentation of its request (as stated in articles 11 and 23 of Regulation N° 1829/2003), we consider important that the guidelines respect the parameters and requirements foresee in the referred legislation, without setting additional requirements.</p> <p>In that regard, it is worth remembering that articles 11 and 23 (2) (c) of Regulation N° 1829/2003, specify that the renewal application must include “any other new information which has become available with regard to the evaluation of the safety in use of the food (or feed) and the risks of the food (or feed) ...”, being focused on the information already available and accessible to the authorization-holder. Consequently, according to the original requisites, it would not be mandatory to present new studies on the safety of the use of the food products/feed and the risks it poses to people or animals and the environment. However, the new guidelines foresee at one end, an active and methodologically structured search of new scientific evidence by the renewal applicant, and on the other, the necessity of providing analysis and various studies as for example, bioinformatics analysis, inter- and intra-species sequences similarities analysis, identification of similarities between new proteins and those allergenic or toxic already known.</p> <p>Due to the above expressed, Argentina suggest nor these neither any other additional requirement being included in the guidelines, and ask them to be adjusted to those included in Regulation N° 1829/2003.</p>
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Umweltbundesamt (Environment Agency Austria) on behalf of the Ministry of Health	AUT	11. New information	<p>Ad 2.4) New Information</p> <p>Unlike the existing Guidance Document for renewal of authorisations the draft Guidance at hand does not demand reports on usage and exposure to be submitted (EFSA 2006, p.3). As the exposure assessment presented in the original application is based on assumptions regarding the future usage, the refinement of this information based on experience during the current authorisation period should be a fundamental part of a renewal application. An appropriate monitoring of exposure under conditions of commercial use is considered a main pillar of a meaningful environmental monitoring that is providing input for further evaluation (Züghart et al. 2011).</p> <p>So as demanded in the existing Guidance Document (EFSA 2006) the following information should be included in renewal applications for GM foods & feeds:</p> <ul style="list-style-type: none"> • reports on the areas and quantity of production, • reports on the importation and utilisation in Europe and • information on known and estimated human and animal exposure. <p>Renewal applications of GMOs authorized for cultivation furthermore should contain the following information:</p> <ul style="list-style-type: none"> • a report on cultivation locations, areas, volume, stewardship and other relevant information related to agricultural practices, • a report on the range and type of specific agronomic practices associated with the event in the range of environments where cultivation occurs. • <p>EFSA (2006): Guidance Document of the Scientific Panel on Genetically Modified Organisms for renewal of authorisations of existing GNO products lawfully placed on the market, notified according to Articles 8 and 20 of Regulation (EC) No 1829/2003, The EFSA Journal (2006) 435, 1-4</p> <p>Züghart, W., Raps, A., Wust-Saucy, A.-G., Dolezel, M., Eckerstorfer, M. (2011): Monitoring of Genetically modified Organisms. A policy paper representing the view of the National Environment Agencies in Austria and Switzerland and the Federal Agency for Nature Conservation in Germany. Umweltbundesamt Wien, Reports, Volume 0305, ISBN: 978-3-99004-107-9</p>
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GM Freeze, EcoNexus, ENSSER, FoE Europe, the Soil Association	GBR	11. New information	<p>PART 1 OF 2</p> <p>The Guidance should make it clear that the search for new information on a GMO must be as wide as possible.</p> <p>Companies want their renewal applications to proceed without a hitch - so, without specific guidance, are likely to seek new information in the narrowest possible range of areas. The experience of renewal applications in the EU is limited but the evidence suggests that information searches are used to confirm the original risk assessment rather than review all research and highlight issues of concern that arise.</p> <p>An example of Monsanto's desire to gloss over less favourable findings came in their 2012 PMEM for MON810. A paper by Gu et al. reported a potentially significant effect in salmon fed on Bt-maize: "The data suggest that Cry1Ab protein or other antigens in Bt-maize have local immunogenic effects in salmon DI. No systemic immune responses could be detected, as indicated by haematology, differential leucocyte counts, plasma clinical chemistry, as well as absence of Cry1Ab-specific antibodies and Cry1Ab protein in plasma. The responses to Bt-maize observed in the present study differed from results from earlier studies in salmon and other animals fed the same event Bt-maize. Longer-term experiments and more in-depth studies on intestinal physiology and immune responses are needed to evaluate health implications". [ref: Gu J, Krogdahl Å, Sissener NH, Kortner TM, Gelencser E, Hemre GI, Bakke AM.,2013. Effects of oral Bt-maize (MON810) exposure on growth and health parameters in normal and sensitised Atlantic salmon, <i>Salmo salar</i> L. British Journal of Nutrition 109 8, 1408-23. doi: 10.1017/S000711451200325X. Available at http://www.ncbi.nlm.nih.gov/pubmed/23182224]</p> <p>It is clear that the authors of the study are calling for more long term research on the feeding of Bt maize, but Monsanto's PMEM report downplayed this, saying "that long-term observations and more in-depth studies on immune response and nutrient utilisation MAY be needed to confirm the results". (our emphasis)</p>
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GM Freeze, EcoNexus, ENSSER, FoE Europe, the Soil Association	GBR	11. New information	<p>PART 2 OF 2</p> <p>In addition, new findings on the survival of GM DNA and proteins in the gut (Spisak et al in 2013, Alexander et al 2007 Agodi et al 2006, Mazza et al 2005) have not so far been covered by PMEM reports from Monsanto despite their relevance to the assumptions in the original risk assessment.</p> <p>[ref 1: Spisák S, Solymosi N, Ittze's P, Bodor A, Kondor D, et al. (2013). Complete Genes May Pass from Food to Human Blood. PLoS ONE 8(7): 69805.doi:10.1371/journal.pone.0069805. ref 2: Alexander, T.W., Reuter, T., Aulrich, K., Sharma, R., Okine, E.K., Dixon, W.T., and McAllister, T.A. (2007). A review of the detection and fate of novel plant molecules derived from biotechnology in livestock production., Animal Feed Science and Technology, 133(1-2), pp. 31-62. Ref 3: Agodi A., Barchitta M., Grillo A. and Sciacca S., 2006. Detection of genetically modified DNA sequences in milk from the Italian market, Int J Hyg EnvironHealth, vol. 209, pp. 81–88, ref 4: Mazza R., Soave M., Morlacchini M., Piva G. and Marocco A., 2005 “Assessing the transfer of genetically modified DNA from feed to animal tissues”, Transgenic Res., 14, 775–784]</p> <p>Data from the monitoring of the agro-ecosystem, food and feed should also feature in renewal applications. To date MON810 PMEM reports have only looked at the development of pest resistance. There has been no attempt by Monsanto to monitor non-target species in areas where the crop is grown, despite a request from EFSA. This raises concern about the applicants' role in seeking new information, prompting the question: WOULD PUBLIC HEALTH AND ENVIRONMENTAL PROTECTION BE BETTER SERVED BY GIVING THIS TASK TO AN INDEPENDENT PUBLIC BODY? This approach, funded by an application fee, could be cost neutral for the applicants through reduced internal costs of monitoring and assessing new findings. Some findings would be relevant to more than one GMO and, if placed on an accessible public website, could assist farmers in deciding whether or not to grow GM crops. An independent monitoring body would also go some way to restoring public faith in the GMO regulatory system and would be able to intervene if new information indicated that the GMO was unsafe. This could trigger the safeguard clause and possibly lead to the withdrawal of the approval. Industry could, of course, continue to generate their own information and evidence if they so wished.</p>
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ANSES - French Agency for Food, Environmental and Occupational Health & Safety	FRA	11. New information	Before line 162 : add a general paragraph saying that the renewal application should be accompanied by any new information available about the GM food and/or feed. For instance, the 2 first paragraphs of section 3.2.4 "Any other information" from the EFSA 2006 Guidance document for renewal of authorisations could be adapted as follows : "New developments that have occurred since the first authorisation of the product and which could have an impact on the risk assessment must be taken into consideration when assessing the product to be renewed. The application for renewal shall therefore be accompanied by any new information which has become available during the authorisation period with regard to the safety of the GM product for humans and animals (food and feed) and for the environment. The applicant shall specifically consider whether new developments in molecular characterization, biochemistry, toxicology, allergenicity, impact on biodiversity, environmental risk assessment, changes to biotic and abiotic factors and long term effects or any methodological developments, such as strategies for data base searches, could provide new information relevant for the risk assessment."
EuropaBio	BEL	11. New information	Line 161: "New information" Replace with: "Any other new information, which has become available" Justification: The guidance document cannot require information which goes beyond the boundaries of what is mandated by law. Articles 11(2)(c) and 23(2)(c), respectively, limit "new information" to what has already become available to the authorisation holder. The Regulation does not provide for a request to generate new data for the purpose of renewal, unless of course the evaluation of the available information identifies any new safety issues which would question the conclusions of the original safety assessment.
Ministry of Agriculture	HUN	12. Systematic search and evaluation of literature	Lines 166 and 167: To keep to transparency and independence the applicant should just retrieve the publications without any selection. All data should be submitted and the evaluation/selection should be performed by the risk assessors of EFSA and of the Member States. Line 174: Copies of all relevant papers should be provided.
Defra	GBR	12. Systematic search and evaluation of literature	Line 163: Where the guidance implies that EFSA has a specific requirement in mind, such as 'all relevant scientific databases should be searched', it would be helpful to be more precise. Otherwise, it is preferable to explain what EFSA will be looking for when assessing applications for renewal (and possibly requesting that applicants explain their approach).

Istituto Superiore di Sanità	ITA	12. Systematic search and evaluation of literature	In this context, also the applicability of the validated analytical method should be evaluated according to Article 8 of the Commission Implementing Regulation (EU) No 503/20138 where the specifics for the methods of detection, identification and quantification of GM food or feed are laid down. The evaluation should consider the technological advances that allowed the identification of technical problems in the original validated methods which, at the time of first validation, could not be identified e.g., reference gene copy number, sub-optimal reference gene assays, commercial unavailability of some reagents, real-time PCR machines not anymore on the market, delta-Ct methods not anymore implementable due to the lack of CRMs, etc.
Federal Office of Consumer Protection and Food Safety (BVL)	DEU	12. Systematic search and evaluation of literature	<p>Line 163-164: What is meant by “all relevant scientific databases”? EFSA should clarify whether this refers only to literature databases (or even databases containing peer-reviewed literature) and, in addition, give examples for suitable databases.</p> <p>Line 167-169: We support that applicants must perform a systematic search and evaluation of literature which could make use of the systematic literature search that has to be performed anyway within the monitoring report each year according to the EFSA GD PMEM. In this context, it makes sense that applicants should also apply criteria for the search strategy. However, we like to point out that applicants do not necessarily have to do a systematic review in the full meaning of the respective EFSA GD: The topics addressed by a renewal application are usually too broad in scope to warrant the application of the systematic review methodology which is in need of a rather specific review question.</p> <p>Line 172: EFSA should specify the phrase “all literature” (if applicable, by adding “peer-reviewed”, “available”, etc.).</p>
Umweltbundesamt (Environment Agency Austria) on behalf of the Ministry of Health	AUT	12. Systematic search and evaluation of literature	<p>Line 163 Regarding the systematic search and evaluation of literature the draft Guidance requires ‘all relevant scientific databases’ to be searched. However it is unclear which databases are considered as relevant. Thus either a specification of what is considered relevant should be provided or the applicants should be asked to provide a justification for their selection of databases.</p> <p>Line 167 The draft Guidance refers to the EFSA Guidance on the application of systematic review methodology to food and feed safety assessment. A footnote providing reference to the respective details of this guidance</p>

			document should be added.
GM Freeze, EcoNexus, ENSSER, FoE Europe, the Soil Association	GBR	12. Systematic search and evaluation of literature	<p>2.4.1. Systematic search and evaluation of literature - 1,466 characters</p> <p>The search for new information and data should be as wide as possible. It should not be confined to the GM trait(s) but should consider whole organisms and changes that may arise from the genetic modification, including indirect effects such as reductions in primary production in agro-ecosystems having implications for non-target organisms, toxic effects on non-target organisms, changes in GMO toxicity as a result of environmental interactions, and cumulative effects (for instance the effect of more than one GM herbicide tolerant crop being grown on individual farms, sub regions or regions).</p> <p>The limited experience of PMM and PMEM (largely reports on MON810 maize) and of renewal applications suggests that consent holders are likely to limit the scope of their literature reviews and play down any findings or trends that may impact on re-approval. Therefore, it is essential that the guidance emphasises the importance of the widest possible literature search.</p> <p>PAGE 8, LINE 169: Add: Applicants should also indicate where the research was carried out and whether it was funded by industry, including themselves. Furthermore, applicants should not attempt to reflect a consensus where indeed there is no scientific consensus.</p> <p>PAGE 8, LINE 175: Add a new sentence requiring companies to list any feeding trials that have been carried out with the GM event since first approval, including both published and non-published company (and company financed) trials as well as trials conducted by third parties.</p>
ANSES - French Agency for Food, Environmental and Occupational Health & Safety	FRA	12. Systematic search and evaluation of literature	<p>Line 169 : add the reference "European Food Safety Authority; Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal 2010; 8(6):1637." in a footnote at the end of line 169.</p> <p>Line 176 : remove "molecular characterisation," from the sentence "... relevant for the molecular characterisation, GM food and feed safety assessment..." (proposed final version : "... relevant for the GM food and feed safety assessment...").</p>

EuropaBio	BEL	12. Systematic search and evaluation of literature	<p>Lines 176-178: “molecular characterisation, GM food and feed safety assessment and environmental risk assessment”</p> <p>Replace with: “evaluation of the safety in use of the food/feed and the risks of the food/feed to the consumer, animals, or the environment”.</p> <p>Justification: It is most appropriate to use the wording from Articles 11 and 23 (2)(c) of Regulation (EC) No 1829/2003.</p> <p>Justification: It is most appropriate to use the wording from Articles 11 and 23 (2)(c) of Regulation (EC) No 1829/2003.</p>
German Federal Agency for Nature Conservation	DEU	12. Systematic search and evaluation of literature	We want to point out that one of the mandatory requirements of an approval of a GMO should be the public availability of its plant material to allow independent research. Otherwise a bias in performed studies will be difficult to avoid.
German Federal Agency for Nature Conservation	DEU	12. Systematic search and evaluation of literature	We want to point out that one of the mandatory requirements of an approval of a GMO should be the public availability of its plant material to allow independent research. Otherwise a bias in performed studies will be difficult to avoid.
Ministry of Agriculture	HUN	13. Updated bioinformatics	Lines 203-205: The likelihood of gene transfer from plant material to the microorganisms present in the receiving environment(s) (e.g. into soil, or inside the gastro-intestinal tract of human or animals fed GM food/feed) can be measured and determined experimentally. It is suggested that to evaluate the consequences of horizontal gene transfer for human and animal health and the environment, those data should be determined experimentally.
Defra	GBR	13. Updated bioinformatics	We also do not consider it appropriate in each case to require a re-evaluation of the consequences of HGT. If the original risk assessment established that the transfer of DNA from the GM plant material to microorganisms is very unlikely to pose a risk to human/ animal health (even if it did occur), there is no reason to require an ‘updated bioinformatics analysis’. We found the discussion on assessing the impacts of HGT at EFSA’s scientific network very useful in highlighting the problems with adopting a bioinformatics approach to addressing the issue of HGT.
VIB	BEL	13. Updated bioinformatics	<p>2.4.2. Updated bioinformatics</p> <p>It is sufficient when the updated bioinformatics analysis is done with the sequence provided in the original application.</p> <p>In a renewal application one cannot ask for a type of information that one did not have to provide in the original application. The renewal application should therefore not ask for “Information on similarities of</p>

			inserted plant DNA sequences with microbial DNA sequences”
Belgian Biosafety Advisory Council	BEL	13. Updated bioinformatics	<p>We do support the request for asking an updated bioinformatics analyses for similarity with known allergenic or toxic proteins as this supports the risk assessment. However, we’re of the opinion that this analyses can be done with the sequence provided in the original application.</p> <p>The request “Information on similarities of inserted plant DNA sequences with microbial DNA sequences” seems to be a new requirement to assess “the likelihood of gene transfer from plant material to microorganisms”. We want to point out that we consider the determination of the potential of the trait to impact human and animal health in the case of horizontal transfer, a more pragmatic way to determine risks. In other words, if the trait is not expected to cause risks to human and animal health, we do not see why this information should be requested.</p>
Spanish National Commission on Biosafety	ESP	13. Updated bioinformatics	<p>Regulation EC N° 1829/2003 establishes that the applicant should provide “any other new information, which has become available”, it does not ask for new assays, if there are no evidences of any possible change in the conclusions of the original RA. Monitoring schemes are designed to detect these hypothetical unexpected changes. New assays should been required only if some evidence is found in the monitoring reports.</p> <p>The bioinformatic analysis of the flanking sequences aims to identify unexpected effects due to the insertion of the DNA in a specific point. In the initial application, it is complemented by agronomic – phenotypic characterization plus compositional analysis, also aimed to the identification of these hypothetical unexpected effects. The applicant also has to provide data supporting the stability of the event. But after 10 years of use, the bioinformatic analysis lacks of value, comparing with the characterization that a crop undergoes in the process of its cultivation, and the results of the monitoring schemes.</p>
Spanish National Commission on Biosafety	ESP	13. Updated bioinformatics	<p>Regulation EC N° 1829/2003 establishes that the applicant should provide “any other new information, which has become available”, it does not ask for new assays, if there are no evidences of any possible change in the conclusions of the original RA. Monitoring schemes are designed to detect these hypothetical unexpected changes. New assays should been required only if some evidence is found in the monitoring reports.</p> <p>The bioinformatic analysis of the flanking sequences aims to identify unexpected effects due to the insertion of the DNA in a specific point. In the initial application, it is complemented by agronomic – phenotypic characterization plus compositional analysis, also aimed to the identification of these hypothetical unexpected effects. The applicant also has to provide data supporting the stability of the event. But after 10 years of use, the bioinformatic analysis lacks of value, comparing with the characterization that a crop undergoes in the process of its cultivation, and the results of the monitoring schemes.</p>

National Institute of Public Health and the Environment	NLD	13. Updated bioinformatics	EFSA requests information on the similarity of inserted DNA sequences with microbial DNA sequences to determine the likelihood of horizontal gene transfer. In the risk assessment the likelihood is not the first, but the second step. According to our understanding, the first step in the risk assessment is to determine whether the inserted sequences could pose a hazard for humans, animals and the environment after their horizontal transfer. On a case-by-case basis, only if a hazard is identified, the likelihood is to be considered. Therefore EFSA is requested to explain why this information on the likelihood of horizontal gene transfer is requested on a mandatory basis
Federal Office of Consumer Protection and Food Safety (BVL)	DEU	13. Updated bioinformatics	Line 201-206: EFSA should clarify whether, in its opinion, bioinformatics analysis is mandatory to “provide information on the similarities of inserted plant DNA sequences with microbial DNA sequences”. In our opinion, a narrative description of the insert(s) is generally sufficient. The possibility for horizontal gene transfer to microorganisms should be tested for by bioinformatics analysis only in cases where the inserted genes pose a risk to human and animal health or the environment.
Umweltbundesamt (Environment Agency Austria) on behalf of the Ministry of Health	AUT	13. Updated bioinformatics	Line 186 The acronym ‘EST’ should be explained. Line 189 The term ‘such a study’ should be specified as regards its objective: similarity searches. Line 196 The draft Guidance refers to ‘relevant EFSA Guidance Documents for the risk assessment for food and feed from GM plants and the assessment of allergenicity’ without specifying them. Footnotes providing full reference details of the respective guidance documents should be added. Lines 208-210 The whole paragraph is very important for the respective chapter and thus should be moved to the beginning of the chapter (line 182).

GM Freeze, EcoNexus, ENSSER, FoE Europe, the Soil Association	GBR	13. Updated bioinformatics	<p>2.4.2. Updated bioinformatics – 1,916 characters</p> <p>Updating of bioinformatics for re-approval of a GMO should be as comprehensive as possible and look at the whole GMO especially in the case of those with stacked GM traits.</p> <p>Stacked GMOs should be treated like any other GMO as a novel organism with multiple traits rather than, as at present by EFSA, where safety is assumed on the basis of testing the individual traits in isolation. In addition, there should be a requirement to investigate possible interactions between the different GM traits present.</p> <p>All types of analysis should be used to detect any changes in the genetic make-up (including epigenetics) of the GMO: changes in protein shape and structure; presence of novel chemicals and potential toxins; changes in nutritional content and quality; changes in anti-nutritional presence and amounts; bioassays on novel chemicals and proteins; and chemical and pesticide residues.</p> <p>Bioinformatic information should also include the expression of the GM protein under different conditions likely to be experienced in the field (eg heat, cold, and disease stress as well as pesticide/herbicide stress) and in different part of the plant (eg pollen, roots, leaves and grain/seed).</p> <p>Another requirement should be the listing of pesticide residue burdens (including herbicide residues) found in GM plants/crops and a comparison of altered transcriptomes and proteomes of high pesticide residue plants/crops as compared to unsprayed plants/crops.</p> <p>PAGE 8, LINE 202: either replace “DNA” with “genetic material” or add “RNA”, as not all microbial genetic sequences are DNA.</p> <p>PAGE 8, LINE 208-210: Previous sequence identity and identification data should also be included. There is likely to be a mix of old (original application) and new sequences (renewal application) present in crops/food/feed covered under the renewal application, as changes may have taken place in some multiplication lines, but not necessarily all.</p>
National Food Institute	DNK	13. Updated bioinformatics	<p>There is no scientific documentation known to us indicating that information on the similarities of inserted plant DNA sequences with microbial DNA sequences could improve the risk assessment output in any way.</p>

ANSES - French Agency for Food, Environmental and Occupational Health & Safety	FRA	13. Updated bioinformatics	<p>Line 181, line 208 : same comment as on line 12 of the Abstract and line 26 of the Summary about the plural form "event(s)". The singular form seems more adapted in this paragraph.</p> <p>Line 184 : replace "insert" by "insert(s)" in the sentence "... the regions flanking the insert and an analysis of..." (proposed final version : "... the regions flanking the insert(s) and an analysis of...").</p> <p>Line 188 : replace "relevant" by "significant" in the sentence "... the newly expressed proteins show relevant similarity with..." (proposed final version : "... the newly expressed proteins show significant similarity with...").</p> <p>Lines 191 and 192 : replace twice "inserts" by "insert(s)" and remove the coma after "the flanking DNA," (proposed final version : "... present within the insert(s) and spanning the junctions between the insert(s) and the flanking DNA potentially encode peptides...").</p> <p>Lines 196 and 197 : add the references "EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion on Guidance for risk assessment of food and feed from genetically modified plants. EFSA Journal 2011; 9(5): 2150." and "EFSA Panel on Genetically Modified Organisms (GMO); Draft Scientific Opinion on the assessment of allergenicity of GM plants and microorganisms and derived food and feed. EFSA Journal 2010; 8(7):1700." in footnotes at the end of line 197.</p> <p>Line 208 : add "(insert(s) and flanking sequences)" after "... sequences obtained from the identity confirmation of the event" (proposed final version : "... sequences obtained from the identity confirmation of the event (insert(s) and flanking sequences) presented in the renewal application...").</p>
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EuropaBio	BEL	13. Updated bioinformatics	<p>Lines 181-182: “Applicants are requested to provide updated bioinformatic analyses of the event(s) in the GM food and feed for renewal.”</p> <p>Replace with: “Applicants are requested to provide the most recent bioinformatic analyses available of the event(s) in the GM food and feed for renewal.”</p> <p>Justification: The guidance document cannot require information which goes beyond the boundaries of what is mandated by law. Articles 11(2)(c) and 23 (2)(c) limit “new information” to what has already become available to the authorisation holder. The Regulation does not provide for a request to generate new data for the purpose of renewal, unless of course the evaluation of the available information identifies any new safety issues which would question the conclusions of the original safety assessment. Therefore, applicants should provide the EFSA with the most up-to-date bioinformatics analyses available to them (e.g., bioinformatics analyses generated for stack applications).</p> <p>Furthermore, it is not clear how the results of updated bioinformatics analyses could be of any value for the assessment of a renewal application, taking into account that the product has already been risk assessed (at least once and even more often in the case of a stack event), approved, and no unintended adverse effects of the food and feed were indicated by the post-market monitoring to the consumer or the environment. Even in the unlikely case that e.g. a given protein would show similarities with a (newly identified) toxin, the weight of evidence as outlined in the initial submission would stand firm.</p> <p>Lines 182-195: “The requirements are laid down below: ...”</p> <p>Delete.</p> <p>Justification: These paragraphs are redundant. See justifications to lines 181-182 above and lines 196-197 below.</p> <p>Lines 196-197: “For these searches, applicants should follow relevant EFSA Guidance Documents for the risk assessment of food and feed from GM plants and the assessment of allergenicity.”</p> <p>Replace with: “Newly generated bioinformatics analyses, where appropriate, should follow relevant EFSA Guidance Documents for the risk assessment of food and feed from GM plants and the assessment of allergenicity.”</p>
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			<p>Justification: See justification to lines 181-182 above.</p> <p>Lines 198-200: Delete paragraph.</p> <p>Justification: See justification to lines 181-182 above.</p> <p>Lines 201-206: “In addition, ...”</p> <p>Replace with: “In addition, when available, applicants should provide information on the similarities of inserted plant DNA sequences with microbial DNA sequences. In this case, applicants should assess whether this information would alter the assessment of the likelihood of gene transfer from plant material to the microorganisms present in the receiving environment(s) (e.g. into soil, or inside the gastro-intestinal tract of human or animals fed GM food/feed), and should evaluate the consequences of horizontal gene transfer for human and animal health and the environment.”</p> <p>Justification: See justification to lines 181-182 above. According to Articles 11(2)(c) and 23(2)(c) of Regulation (EC) No 1829/2003 only reports available to the authorisation holder and based on available sequences are required to be provided. New bioinformatics analyses do not have to be generated for the purpose of a renewal.</p> <p>Lines 208-210: Delete paragraph</p> <p>Justification: See justification to lines 181-182 above. According to Articles 11(2)(c) and 23(2)(c) of Regulation (EC) No 1829/2003 only reports available to the authorisation holder and based on available sequences are required to be provided. New bioinformatics analyses do not have to be generated for the purpose of a renewal.</p>
Testbiotech	DEU	13. Updated bioinformatics	<p>The applicant should also provide updated information on new RNAs emerging from the insertion of the DNA construct, and assess whether this RNA might give rise to proteins or interact with gene regulation (RNAi). Possible hazards should be characterised if, for example, the regulatory miRNA is transmitted via food chain.</p>

German Federal Agency for Nature Conservation	DEU	13. Updated bioinformatics	<p>Lines 183-187:</p> <p>The assessment of potential gene interruption due to insertion should not only consider flanking regions. In order to determine if rearrangements of the plant genome occurred at the insertion site, the plant sequence pre-insertion has to be analysed as well. Comparison of this sequence to the flanking regions should reveal if any rearrangements/changes were caused by the insertion. Only with the pre-insertion sequence meaningful bioinformatic analyses can be performed concerning the interruption of potential ORFs or regulatory sequences by the insertion.</p>
German Federal Agency for Nature Conservation	DEU	13. Updated bioinformatics	<p>Lines 183-187:</p> <p>The assessment of potential gene interruption due to insertion should not only consider flanking regions. In order to determine if rearrangements of the plant genome occurred at the insertion site, the plant sequence pre-insertion has to be analysed as well. Comparison of this sequence to the flanking regions should reveal if any rearrangements/changes were caused by the insertion. Only with the pre-insertion sequence meaningful bioinformatic analyses can be performed concerning the interruption of potential ORFs or regulatory sequences by the insertion.</p>
Testbiotech	DEU	14. Additional documents or studies performed by the applicant or third party	<p>The applicant should also provide data on the amounts of herbicides or other chemicals applied under the conditions of regional agricultural practices. It should be reported if herbicide resistant weeds are observed that might make a higher dosage of herbicide necessary, and data should be provided on residue levels of pesticides under the various conditions. Potential interactions from the residues with other plant constituents should be discussed.</p> <p>The applicant should report if there is any observation of transgene flow to native populations or any emergence of feral populations. It should be determined whether these observations are caused by cultivation and/ or spillage from transport and / or other reasons.</p> <p>The applicant should systematically collect data from any animal health services that can provide data on developments in the health of animals fed with the GMOs.</p> <p>The applicant should provide data on extreme weather conditions that occurred in regions where the GMOs are cultivated, and on any observations that are related to genome x environment interactions.</p> <p>If other genetically engineered crops are growing or fed at the same time possible interactions between the traits, for example, in food and feed have to be discussed.</p>

Ministry of Agriculture	HUN	14. Additional documents or studies performed by the applicant or third party	After a GMO was authorized as animal feed, additional feeding studies performed with the target species should be provided if available.
Defra	GBR	14. Additional documents or studies performed by the applicant or third party	Lines 221 – 226: We do not consider that these data are necessary to ‘further support’ the risk assessment. If there is evidence that spilled grain containing the GM event may be linked to increased adverse environmental effects compared to non-GM grain, this must be reported etc. but asking for data on agronomic characteristics per se. appears to be more of an academic exercise. EFSA’s stringent requirements for the provision and analysis of such data is likely to preclude its submission.
VIB	BEL	14. Additional documents or studies performed by the applicant or third party	2.5. Additional documents or studies performed by the applicant or third party It should not be necessary to submit as part of a renewal application information on all submissions for market approvals and pending authorisations in other jurisdictions. This has no business whatsoever with determining whether or not there is any information that the conclusions of the original risk assessment are still valid.
Belgian Biosafety Advisory Council	BEL	14. Additional documents or studies performed by the applicant or third party	EFSA asks for a list of all authorisations granted, all applications under assessment and unsuccessful applications. We do not see how this information will aid in the renewal of a GM event that has already been assessed by EFSA for its food/feed safety. We want to note that there is a legal obligation to report on restrictions imposed by third countries. Art. 9.3 and Art 21.3 of Regulation (EC) No. 1829/2003 state: In particular, the authorisation-holder shall forthwith inform the Commission of any prohibition or restriction imposed by the competent authority of any third country in which the food/feed is placed on the market. To be in line with the legislation, it would be better to only request to report on those authorisations for which restrictions have been imposed. Further, for a GM event that already has been authorised, according to the legislation Art. 9.3 and Art 21.3 of Regulation (EC) No. 1829/2003: The authorisation-holder shall forthwith inform the Commission of any new scientific or technical information which might influence the evaluation of the safety in use of the food/feed. EFSA requests in his GD for “any relevant information gained from the introduction of the event into other varieties”. The request of EFSA “to provide any relevant information (line 223)” is not in line with the legislation. Hence, we propose to rephrase lines 222-225 according to Art. 9.3 and 21.3.

National Institute of Public Health and the Environment	NLD	14. Additional documents or studies performed by the applicant or third party	<p>It is stated that applicants should consider relevant documents or studies on the GM food and feed for renewal produced since the publication of the most recent EFSA opinion. Applicants are to provide ‘any relevant information gained for the introduction of the event in to other varieties, such as protein expression levels or agronomic and compositional characteristics that could further support the evaluation of the GM food and feed.’</p> <p>We wonder why this information is relevant in relation to food, feed and environmental safety? Can EFSA explain what the relevance is to collect these data in addition to the data as requested in the literature review (2.4.1)?</p>
Federal Office of Consumer Protection and Food Safety (BVL)	DEU	14. Additional documents or studies performed by the applicant or third party	<p>Line 221: The term “relevant information” does not provide adequate guidance to applicants or risk assessors: EFSA should specify what criteria are important to assess whether a document or an information is “relevant” with regard to the evaluation of the safety in use of the food/feed and the risks of the food/feed to animals, humans or the environment. The question arises whether all studies that do not meet the high standards of the current EFSA guidance documents (e.g. specific requirements for the experimental design of field trials or animal studies) are irrelevant for a significant risk assessment.</p> <p>Line 222-225: According to the assessment concept given in EFSA Guidance documents, data on agronomic and compositional characteristics give only meaningful (and therefore “relevant”) information, if they are produced in properly designed field trials containing a suitable comparator. It is not to be expected, that these conditions are met by state-of-the-art variety trials for commercial applications, as proper comparators will generally not be grown within these trials. Nor will protein expression levels be measured routinely. Therefore, data from variety trials cannot inform the risk assessment of the event in respect to protein expression levels or agronomic and compositional characteristics with the quality standard set by EFSA itself. “Other varieties” is the wrong wording here anyway, as no “variety” was approved by the authorization, only an event was authorized. Please discriminate between event, variety and line. It follows, that this sentence should be omitted.</p> <p>Line 221-226: EFSA should keep in mind that there may be cases where the applicant has no access to certain additional documents or studies performed by third parties. Therefore, it should be made clear that submission is only possible for documents or studies which are available to the applicant.</p>

GM Freeze, EcoNexus, ENSSER, FoE Europe, the Soil Association	GBR	14. Additional documents or studies performed by the applicant or third party	<p>2.5. Additional documents or studies performed by the applicant or third party – 1,149 characters</p> <p>PART 1 OF 2</p> <p>WHOLE SECTION</p> <p>All research carried out on a GMO by applicants should be made available to EFSA and the public regardless of whether or not the results have been published or are incorporated in the final risk assessment. This should be made mandatory as it would assist the regulatory process. Greater transparency would also help restore public faith in the regulatory system.</p> <p>There is a growing volume of research carried out by independent scientists into the safety of GMOs, despite difficulties in obtaining samples of GM crops/feed and their conventionally bred isogenic parent. In the past GMO research from independent scientists has often not been treated as equal to that carried out by or through the applicants to support their own application. The reasons for this are not entirely clear but may in part be due to independent researchers at times adopting different methodologies. When GMOs are being assessed for re-approval it is essential that peer-reviewed third party research is given at least equal weight to data from applicants (which is often not peer reviewed). Lack of consensus is a scientific reality and should be dealt with as such.</p>
GM Freeze, EcoNexus, ENSSER, FoE Europe, the Soil Association	GBR	14. Additional documents or studies performed by the applicant or third party	<p>2.5. Additional documents or studies performed by the applicant or third party – 3,297 characters</p> <p>PART 2 OF 2</p> <p>WHOLE SECTION</p> <p>In the case of herbicide tolerant GM crops, monitoring should also cover, as mandatory element, the use and movement in the environment of the associated herbicide, whether under the Plant Protection Productions regulatory process (Regulation (EC) No 1107/2009), or via the renewals process. There is no denying that the approval of HT crops would greatly increase the environmental, farm animal and human exposure to a particular herbicide (the amounts detected would depend on farmer take up and how it was used). With Roundup Ready (RR) crop imports for feed, permitted and actual glyphosate residues in soya from North and South America are far higher than the EU and internationally agreed maximum residue levels (MRL) [ref: http://www.testbiotech.de/sites/default/files/TBT_Background_Glyphosate_Argentina_0.pdf]. This makes it essential that PMM and PMEM include routine monitoring of residues to ensure that they are below EU MRL. Animals fed on RR soya should also be monitored to ensure that they are healthy. As far as we know, monitoring of herbicide residues in animal feed or dairy products, meat and eggs does not currently</p>

			<p>take place in the EU. Other monitoring of food for herbicide residues by member states is patchy across the EU. It would therefore appear that animal products derived from animals fed GM HT soya are not currently monitored for herbicide residues.</p> <p>Greenpeace estimates that, if the expansion of RR soya, maize and sugar beet crops witnessed in North and South America were repeated in the EU, glyphosate usage in the EU would rise by 800% and consequently residues in feed and food would also rise. [ref: http://www.greenpeace.org/international/Global/international/publications/agriculture/2012/438-Benbrook-Report-Summary.pdf] The limited monitoring of humans and farm animals for glyphosate residues which has been carried out to date has been done by independent scientists [ref: Krüger M., Schledorn P, Schrödl W, Hoppe H-W, Lutz and Shehata AA, 2014. Detection of Glyphosate Residues in Animals and Humans journal of Environmental Analytical Toxicology 4:2 http://dx.doi.org/10.4172/2161-0525.1000210] and NGOs [ref: Medical Laboratory Bremen, 2013. Determination of Glyphosate residues in human urine samples from 18 European countries. Available at https://www.foeeurope.org/sites/default/files/glyphosate_studyresults_june12.pdf]. All samples have confirmed the presence of glyphosate in human and farm animal urine, emphasising the need for exposure to be monitored by official bodies in the EU on a regularly basis to feed into the GMO and pesticide approvals process.</p> <p>PAGE 9, LINE 218 Please replace ‘mention’ with ‘include’ and add ‘and withdrawals’ after ‘applications’ to read in full: “The list should also include unsuccessful applications and withdrawals, providing the reasons...”</p> <p>PAGE 9, LINE 226 We suggest a new section 2.6, which would require data on the change of agricultural practices due to the production of the GMO currently seeking renewal. This should include changes in pesticide regimes, such as increased levels and mixes of herbicides (eg 2,4-D) due to increased herbicide tolerance in weeds, in order to be able to test for the relevant residues and to enable customers/consumers to make informed choices.</p>
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ANSES - French Agency for Food, Environmental and Occupational Health & Safety	FRA	14. Additional documents or studies performed by the applicant or third party	<p>Title : add "a" before "third party" (proposed final version : "2.5. Additional documents or studies performed by the applicant or a third party").</p> <p>Line 217 : same comment as on line 12 of the Abstract and line 26 of the Summary about the plural form "event(s)". The singular form seems more adapted in this paragraph.</p> <p>Line 226 : add elements that were present in the EFSA 2006 Guidance document for renewal of authorisations and should be present (either mandatory for some of them, or if the applicant has new information in the other cases) in this new Guidance document. For instance add the following sentence : "The applicant shall submit the following or otherwise give justifiable reasons for not providing the information requested:</p> <ol style="list-style-type: none"> 1. a report on the areas and quantity of production, the importation and utilisation in Europe and information on known and estimated human and animal exposure, 2. updated information on the levels of expression of the specific proteins and metabolites resulting from the genetic modification and on the composition of the GMO, if available, 3. updated information on allergenicity and toxicology, if available, 4. a report on the stability of the trait and the methods for detection over the authorisation period, 5. a report on any observed unintended and/or unanticipated effects, 6. a report on cultivation locations, areas, volume, stewardship and other relevant information related to agricultural practices, 7. a report on the range and type of specific agronomic practices associated with the event in the range of environments where cultivation occurs. The report should assess the impact on the agricultural and surrounding environments, including for example examination of possible cumulative effects of growing the event over several years, 8. a report on interactions that might take place with present cultivars, whether GM or not, and the possible agronomic and environmental consequences of these interactions which may require changes in cultivation, harvesting or processing, <p>Where applicable, reports submitted shall include methods, raw data, results, conclusions and recommendations."</p>
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EuropaBio	BEL	14. Additional documents or studies performed by the applicant or third party	<p>Lines 212-213: “Applicants are requested to report any authorisations for the GM food and feed granted by third countries.”</p> <p>Replace with: “Applicants are requested to report any authorisations for the GM food and feed granted by third parties for the time period between the authorisation granted in the EU and the submission of the renewal application.”</p> <p>Justification: An indication of the timeframe, necessary for reasons of legal certainty, is absent. Nonetheless, it is unclear to what extent the information on the authorisation status in countries outside the EU adds value to the assessment of a renewal application or is consistent with the requirements of an EU regime. This is confirmed by Article 9(3) and 21(3) which only require notification of “any prohibition or restriction imposed by...any third country” and not information as regards non-EU authorisations per se.</p> <p>Lines 216-219: Delete paragraph.</p> <p>Justification: Articles 11(2)(c) and 23(2)(c) of Regulation (EC) No 1829/2003 limit the scope of “new information” accompanying a renewal application to what is relevant for the evaluation of the safety in use of the food and feed and the risks to animals, humans or the environment.</p> <p>Replace Lines 221-222 with: “Applicants should consider studies on the GM food and feed for renewal relevant for the evaluation of its safety, produced since the publication of the most recent EFSA scientific opinion on a product that includes the event(s) for renewal.”</p> <p>Justification: Articles 11(2)(c) and 23(2)(c) already limit the scope of “new information” which has to accompany a renewal application to what is relevant for the evaluation of the safety in use of the food and feed and the risks of the food and feed to animals, humans or the environment. A timeframe is needed and it appears reasonable to consider the latest EFSA Opinion on a product that includes the event(s) for renewal, for example in the context of stacked event applications.</p> <p>Delete the sentence in Lines 222-225.</p> <p>Justification: Any study conducted and provided to regulatory authorities relates to the GM event and is irrespective of the genetic background. Regulation (EC) No 1829/2003 does not relate to variety registration, hence data for a GM food and feed in other varieties is irrelevant for the renewal of a GM food and feed. Articles 11(2)(c) and 23(2)(c) limit the scope of “new information” which has to accompany a renewal</p>
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			<p>application to what is relevant for the evaluation of the safety in use of the food and feed and the risks of the food and feed to animals, humans or the environment. However, any data generated in variety trials is linked to the performance of the variety (e.g., DUS testing, i.e. Distinctness, Uniformity and Stability) and no data on the safety of a transformation event are generated per se. In addition, different study designs for variety testing in different countries of cultivation would render valid scientific comparisons impossible.</p> <p>Furthermore, transformation events are introduced into other varieties by conventional breeding. Regulation (EC) No 1829/2003 (relying on Article 2(2) of Directive 2001/18/EC) explicitly excludes from its scope naturally occurring alterations by mating and/or natural recombination. Consequently, after the GMO product was originally safety assessed it was approved without any restriction in terms of breeding into different genetic backgrounds (varieties) and any (potential) consequent alterations (e.g. of protein expression levels or agronomic and compositional characteristics), which are naturally occurring.</p> <p>In conclusion, information about varieties cannot substantially add to the validation of the original safety assessment in the frame of a renewal application.</p>
German Federal Agency for Nature Conservation	DEU	14. Additional documents or studies performed by the applicant or third party	<p>Several relevant new EFSA Guidance Documents (EFSA 2010, EFSA 2011a, EFSA 2011b, EFSA 2011c) and the implementing Regulation (EC) No 503/2013 have become available since the introduction of Regulation (EC) No 1829/2003. That shows that standards for requirements in applications developed during this time. Therefore the original application may not meet the current standards. In that case the renewal application must be amended to suit the current requirements.</p> <p>The applicant should provide any new information concerning the event for which renewal of the application is sought. This should not be limited to the literature research, the monitoring and performed studies, but include any data or incidence that may have the potential to change or confirm the GM food and feed safety assessment and the environmental risk assessment.</p> <p>In the original application exposure of human and animals and the environment where only estimated. Therefore the following information obtained during the time of use of the product and also demanded in the current Guidance Document (EFSA 2006) should be given by the applicant:</p> <ul style="list-style-type: none"> • a report on the areas and quantity of production, the importation and utilization in Europe and information on known and estimated human and animal exposure, <p>In case of cultivation</p> <ul style="list-style-type: none"> • a report on cultivation locations, areas, volume, stewardship and other relevant information related to agricultural practices, • a report on the range and type of specific agronomic practices associated with the event in the range of environments where cultivation occurs. The report should assess the impact on the agricultural and surrounding environments, including for example examination of possible cumulative effects of growing the

		<p>event over several years,</p> <ul style="list-style-type: none"> • a report on interactions that might take place with present cultivars, whether GM or not, and the possible agronomic and environmental consequences of these interactions which may require changes in cultivation, harvesting or processing, <p>References:</p> <ul style="list-style-type: none"> • EFSA (2006): Guidance Document of the Scientific Panel on Genetically Modified Organisms for renewal of authorisations of existing GNO products lawfully placed on the market, notified according to Articles 8 and 20 of Regulation (EC) No 1829/2003, The EFSA Journal (2006) 435, 1-4 • EFSA (2010): Scientific Opinion on Statistical considerations for the safety evaluation of GMOs. The EFSA journal, 8(1):1250. [59 pp.]. doi:10.2903/j.efsa.2010.1250 • EFSA (2011a): Scientific Opinion on Guidance for risk assessment for food and feed from genetically modified plants. EFSA Journal 2011; 9(5):1250 [37pp.] doi:10.2903/J.efsa.2011.2150. • EFSA (2011b): Guidance Document on Selection of Comparators for the Risk Assessment of GM Plants. EFSA Journal 2011; 9(5):2149. [21 pp.] doi:10.2903/j.efsa.2011.2149. • EFSA (2011c): Guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants. EFSA Journal 2011; 9(8): 2316. [40 pp.] doi:10.2903/j.efsa.2011.2316. • EFSA GMO Panel (2014): Draft Guidance for Renewal Applications of Genetically Modified Food and Feed authorised under Regulation (EC) No 1829/2003. <p>http://www.efsa.europa.eu/en/consultations/call/141104.pdf</p>
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German Federal Agency for Nature Conservation	DEU	14. Additional documents or studies performed by the applicant or third party	<p>Several relevant new EFSA Guidance Documents (EFSA 2010, EFSA 2011a, EFSA 2011b, EFSA 2011c) and the implementing Regulation (EC) No 503/2013 have become available since the introduction of Regulation (EC) No 1829/2003. That shows that standards for requirements in applications developed during this time. Therefore the original application may not meet the current standards. In that case the renewal application must be amended to suit the current requirements.</p> <p>The applicant should provide any new information concerning the event for which renewal of the application is sought. This should not be limited to the literature research, the monitoring and performed studies, but include any data or incidence that may have the potential to change or confirm the GM food and feed safety assessment and the environmental risk assessment.</p> <p>In the original application exposure of human and animals and the environment where only estimated. Therefore the following information obtained during the time of use of the product and also demanded in the current Guidance Document (EFSA 2006) should be given by the applicant:</p> <ul style="list-style-type: none"> • a report on the areas and quantity of production, the importation and utilization in Europe and information on known and estimated human and animal exposure, <p>In case of cultivation</p> <ul style="list-style-type: none"> • a report on cultivation locations, areas, volume, stewardship and other relevant information related to agricultural practices, • a report on the range and type of specific agronomic practices associated with the event in the range of environments where cultivation occurs. The report should assess the impact on the agricultural and surrounding environments, including for example examination of possible cumulative effects of growing the event over several years, • a report on interactions that might take place with present cultivars, whether GM or not, and the possible agronomic and environmental consequences of these interactions which may require changes in cultivation, harvesting or processing,
Federal Office of Consumer Protection and Food Safety (BVL)	DEU	15. Risk assessment	<p>Line 227-234:</p> <p>The chapter does not give any supporting guidance how to evaluate or interpret the collected information. Moreover, the term “[new scientific] uncertainties” is very vague and it should be kept in mind that, from a scientifically point of view, 100 percent certainty does not exist.</p>

GM Freeze, EcoNexus, ENSSER, FoE Europe, the Soil Association	GBR	15. Risk assessment	<p>3. Risk assessment – 3,627 characters</p> <p>The risk assessment for re-approval of a GMO should be of the highest standard and should acknowledge where there are data gaps, inadequate data and scientific uncertainty.</p> <p>The risk assessment should assess the whole GM organism and look for and assess unexpected genetic, chemical, compositional and metabolic changes based on a comprehensive analysis using all bioinformatics tools available.</p> <p>It should also consider the potential negative impacts of its associated agricultural practices.</p> <p>The risk assessment should be of the entire GMO on its own and its actual and potential negative impacts. It should not focus just on the intended GM traits as other (unintended) changes are equally relevant. Comparisons between the GMO and its isogenic parent cannot be deemed sufficient, as such comparison cannot provide a full picture. Please also see our comments under 2, mandatory data requirements).</p> <p>Assessment should take into account GMOs which are already approved and released into the environment so that any cumulative and combinatorial effects on health and the environment can be assessed.</p> <p>Cumulative and combinatorial effects are also important in the case of stacked GM crops which may contain several herbicide tolerance and insect resistance traits where the combination may alter the toxicity or allergenicity of the GMOs to humans, animals and non-target species. Data on such effects should be part of both a first application and a renewal application of a GM event.</p> <p>Data gathered during PMEM and PMM by the applicants should be considered in the risk assessment, but not in isolation. Research and data from all sources should be assessed, in combination, including independent environmental and health monitoring data on (amongst other issues) herbicide residues along food chains, insect and weed resistance, soil health, gene transfer, horizontal gene transfer, crop health, indirect effects on the food chain in wild species, and farm animal health and welfare. Data should also be gathered and risk-assessed on gene expression and plant growth in different conditions (eg hot and dry, wet and humid.)</p> <p>The direct and indirect environmental impact of the cultivation of GMOs in non-EU countries should be considered for crops licensed for import. It is unacceptable that the EU should have rigorous requirements for the environmental safety, human and animal health impacts of GMO cultivation in Europe but ignore this</p>
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			<p>issue for imported crops. A particular concern is the intensive use of pesticides, including aerial spraying of herbicide mixes on HT crops and on so-called ‘superweeds’ that have developed as a consequence of the introduction of HT crops.</p> <p>The risk of escapes and gene transfer from imported GM food and feed that also constitute seeds should also be part of the risk assessment.</p> <p>Consideration should be given to the time required for indirect effects to become ecologically and/or socio-economically significant. This is particularly important when the GMO is one of many similar events being grown.</p> <p>Feed and food safety testing are a controversial area of research. Current risk assessments (and hence assessment of re-approvals) rely entirely on short term laboratory feeding trials which are largely designed to detect acute toxicity and have a limited range of parameters and data required. Feeding trials limited to 90 days cannot assess long term toxicity (including low level chronic toxicity), reproductive health impacts, chronic and acute lifetime effects and intergenerational effects. To fully assess the safety of GM feed and food, feeding studies should span at least two years.</p>
ANSES - French Agency for Food, Environmental and Occupational Health & Safety	FRA	15. Risk assessment	<p>Line 231 : add "risk" after "initial" (proposed final version : "... to make an initial risk assessment...").</p> <p>Line 232 : add "and the impacts of a modified exposure, when relevant" after "or uncertainties" (proposed final version : "... to further address any newly characterised hazards or uncertainties and the impacts of a modified exposure, when relevant.").</p>

EuropaBio	BEL	15. Risk assessment	<p>Line 227: “Risk Assessment”</p> <p>Replace with: “Assessment of new information”</p> <p>Justification: The title needs to be in line with Articles 11(2)(c) and 23(2)(c) of Regulation (EC) No 1829/2003.</p> <p>As acknowledged by the EFSA (see Lines 282-230), Articles 11 and 23 of Regulation (EC) No 1829/2003 do not provide for a new risk assessment to be conducted, but rather for a revision of the conditions of the authorisation which were based upon the conclusions of the original risk assessment, based on newly available information. In that sense, applicants should assess whether the collected information affects the validity of the conclusions made during the original safety assessment.</p> <p>Line 230: “assumptions”</p> <p>Replace with: “conclusions”</p> <p>Justification: The conclusions of the original safety assessment are not based on mere assumptions but rather on robust scientific evidence as summarized and presented in the EFSA Opinion which was the basis for the European Commission to issue an authorisation. Please note that the authority can only issue a positive opinion after it has verified (see Articles 6(3)(a) and 18(3)(a) of Regulation (EC) No 1829/2003) that the food or feed complied with Articles 4(1) and 16(1) of this Regulation.</p> <p>Line 232: “characterised”</p> <p>Replace with: “identified”</p> <p>Justification: This clarifies that no new data should be generated for renewal applications. Hazard identification comes before characterisation.</p> <p>Lines 232-234: “When new hazards or uncertainties are identified, the risk assessment may require that new studies are performed in accordance with current legislation and the most recent EFSA guidance documents.”</p> <p>Replace with: “In case the applicant identifies the need to address newly identified hazards and to perform new studies, those should be conducted in accordance with the most recent EFSA guidance documents.”</p>
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Julius Kühn-Institut	DEU	16. Monitoring plan and proposal for improving the conditions of the original authorisation	<p>Lines 240 - 243: If no additional risks/critical uncertainties are defined and if no adverse impacts were observed after 10 years of monitoring, an end of monitoring requirements may also be an option</p>
GM Freeze, EcoNexus, ENSSER, FoE Europe, the Soil Association	GBR	16. Monitoring plan and proposal for improving the conditions of the original authorisation	<p>4. Monitoring plan and proposal for improving the conditions of the original authorisation – 3,133 characters</p> <p>PAGE 9, LINE 238: Add “increased” to read: “If increased, new or additional risks”.</p> <p>Studying the effects of the release of GM food and crops on health and the environment is a complex task. In the future crops on farms could be genetically engineered with a wide range of different traits, such as herbicide tolerance, insect resistance, disease resistance, abiotic stress tolerance and changed nutritional value (if such GM traits become technically possible, are proven safe and are acceptable to the public).</p> <p>Sifting through field and laboratory generated data to pick up on unexpected direct and indirect impacts, possible synergistic effects of genes in stacked GM crops, or arising from hybrid varieties or hybridisation with wild crop relatives, will require a sophisticated approach both to gathering and analysing data.</p> <p>PMEM has only been required for two crops in the EU to date (MON810 maize and BASF’s Amflora potato</p>

			<p>(now withdrawn)). EFSA's suggestion to improve the general surveillance of GMOs in their scientific appraisals of MON810 monitoring reports have so far been rejected by Monsanto (see our comments on 2.3).</p> <p>It would be illogical to imagine that applicants for re-approval of a GMO would make suggestions for making consent conditions more onerous for themselves and it is not a role that they should be asked to fulfil. Furthermore it is unlikely that applicants will be willing to undertake the sort of field monitoring that may be required to detect long-term indirect or synergistic effects between different GM traits. It is worth remembering that during independent monitoring of GM oilseed rape during the UK's government sponsored Farm Scale Evaluation from 1999-2003, a hybrid seed of GM herbicide tolerant oilseed rape and the arable weed Charlock (<i>Sinapsis arvensis</i>) was found. [ref: Daneils R. et al., 2005. The potential for dispersal of herbicide tolerance genes from genetically-modified, herbicide-tolerant oilseed rape crops to wild relatives. Contract reference EPG 1/5/151] Previously this cross was thought to be impossible under field conditions. The implications of arable weeds picking up herbicide tolerance genes in addition to the natural evolution of herbicide resistance, which is already well documented, are significant for farmers (higher costs and more difficult weed control), public health (increased risk of herbicide exposure via air, food and water) and the environment (increased risk of herbicide pollution and damage).</p> <p>Our proposal is therefore for PMEM and PMM to be taken out of the hands of the applicants and into a transparent, publicly accountable independent body specifically set up to carry out this role. That body would also be required to liaise with other national agencies involved in environmental monitoring and surveillance to avoid unnecessary duplication of activities and facilitate collaboration on methodologies and field practice. Applicants for new and re-approvals could be charged an appropriate application and licensing fee to cover the costs of the independent body. They would then be spared the costs of having to do it themselves.</p>
National Food Institute	DNK	16. Monitoring plan and proposal for improving the conditions of the original authorisation	<p>4. Monitoring plan and proposal for improving the conditions of the original authorisation.</p> <p>The content in this section is vague. In this guidance there should be established criteria for termination of monitoring programmes. There are no scientific arguments to have monitoring plans going forever for all GM-plants and for all stacked events. This kind of suggestions or requirements is working against the internationally scientific accepted case by case principle. We must establish a benchmark discriminating between which information is needed and what is just nice to know from monitoring plans. The information needed should be scientifically based and be limited to the information that would reduce uncertainties that case by case was pointed out in the original scientific risk evaluation. Such uncertainties should be compared to uncertainties from growing of traditionally bred crops.</p>

EuropaBio	BEL	16. Monitoring plan and proposal for improving the conditions of the original authorisation	<p>Line 238: “If new or additional risks and/or critical uncertainties linked to the GM food/feed or the environment are identified”</p> <p>Replace with: “If new risks of the GM food/feed to the consumer, animals or the environment are identified”.</p> <p>Justification: The term ‘critical uncertainties’ is entirely ambiguous and does not provide any detailed guidance as required under the general EU law principle of legal certainty. The term ‘additional’ is redundant, as either a risk has already been identified in the original safety assessment or it is newly identified. The expression ‘risks of the GM food/feed to the consumer or the environment’ is in accordance with Articles 11(2)(c) and 23(2)(c) of Regulation (EC) No 1829/2003.</p> <p>Line 244:</p> <p>Add paragraph: “Vice versa, if no new risks of the GM food/feed to the consumer, animals or the environment are identified, applicants may choose to provide a proposal for amending or complementing the conditions of the original authorisation, inter alia the conditions concerning future monitoring.”</p> <p>Justification: Based on the weight of evidence, the likelihood is extremely high that the conclusions of the original risk assessment will be confirmed. Therefore, EFSA should make this very transparent in its guidance document for renewal applications, otherwise EFSA risks that it casts doubt on both the reliability and validity of its original risk assessment and the authorisation issued by the European Commission.</p>
GM Freeze, EcoNexus, ENSER, FoE Europe, the Soil Association	GBR	17. Documentation provided to EFSA	No comments
EELV	FRA	18. References	<p>I dont want any OGM at all in Europe</p> <p>OGM are dangerous</p> <p>I am for bio food Ich bin für die Entwicklung der Bio-Landwirtschaft</p> <p>I dont want that my taxes are used to help OGM</p> <p>Thanks</p> <p>██████████</p>

GM Freeze, EcoNexus, ENSSER, FoE Europe, the Soil Association	GBR	18. References	No comments
German Federal Agency for Nature Conservation	DEU	18. References	<ul style="list-style-type: none"> • EFSA (2006): Guidance Document of the Scientific Panel on Genetically Modified Organisms for renewal of authorisations of existing GNO products lawfully placed on the market, notified according to Articles 8 and 20 of Regulation (EC) No 1829/2003, The EFSA Journal (2006) 435, 1-4 • ESFA (2010): Scientific Opinion on Statistical considerations for the safety evaluation of GMOs. The EFSA journal, 8(1):1250. [59 pp.]. doi:10.2903/j.efsa.2010.1250 • EFSA (2011a): Scientific Opinion on Guidance for risk assessment for food and feed from genetically modified plants. EFSA Journal 2011; 9(5):1250 [37pp.] doi:10.2903/J.efsa.2011.2150. • EFSA (2011b): Guidance Document on Selection of Comparators for the Risk Assessment of GM Plants. EFSA Journal 2011; 9(5):2149. [21 pp.] doi:10.2903/j.efsa.2011.2149. • EFSA (2011c): Guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants. EFSA Journal 2011; 9(8): 2316. [40 pp.] doi:10.2903/j.efsa.2011.2316. • EFSA GMO Panel (2014): Draft Guidance for Renewal Applications of Genetically Modified Food and Feed authorised under Regulation (EC) No 1829/2003. http://www.efsa.europa.eu/en/consultations/call/141104.pdf
German Federal Agency for Nature Conservation	DEU	18. References	<ul style="list-style-type: none"> • EFSA (2006): Guidance Document of the Scientific Panel on Genetically Modified Organisms for renewal of authorisations of existing GNO products lawfully placed on the market, notified according to Articles 8 and 20 of Regulation (EC) No 1829/2003, The EFSA Journal (2006) 435, 1-4 • ESFA (2010): Scientific Opinion on Statistical considerations for the safety evaluation of GMOs. The EFSA journal, 8(1):1250. [59 pp.]. doi:10.2903/j.efsa.2010.1250 • EFSA (2011a): Scientific Opinion on Guidance for risk assessment for food and feed from genetically modified plants. EFSA Journal 2011; 9(5):1250 [37pp.] doi:10.2903/J.efsa.2011.2150. • EFSA (2011b): Guidance Document on Selection of Comparators for the Risk Assessment of GM Plants. EFSA Journal 2011; 9(5):2149. [21 pp.] doi:10.2903/j.efsa.2011.2149. • EFSA (2011c): Guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants. EFSA Journal 2011; 9(8): 2316. [40 pp.] doi:10.2903/j.efsa.2011.2316. • EFSA GMO Panel (2014): Draft Guidance for Renewal Applications of Genetically Modified Food and Feed authorised under Regulation (EC) No 1829/2003. http://www.efsa.europa.eu/en/consultations/call/141104.pdf